THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CIVIL ACTION NO. 09-2073 (WJM)

WARNER CHILCOTT LABORATORIES IRELAND LIMITED, MAYNE PHARMA INTERNATIONAL, PTY, LTD.,
Plaintiffs,
-v-
MYLAN PHARMACEUTICALS, INC., and MYLAN, INC.,
Defendants.

WARNER CHILCOTT LABORATORIES IRELAND LIMITED, MAYNE PHARMA INTERNATIONAL, PTY, LTD.,
Plaintiffs,
-v-
IMPAX LABORATORIES, INC.,
Defendant.

TRIAL

TRANSCRIPT OF PROCEEDINGS

(MORNING SESSION)

February 8, 2012
Newark, New Jersey

B E F O R E: HONORABLE WILLIAM J. MARTINI, U.S.D.J.

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Purusant to Section 753 Title 28 United States Code, the following transcript is certified to be an accurate record taken stenographically in the above entitled proceedings.

s/ John K. Stone
_____
JOHN KEVIN STONE,
Official Court Reporter

I_N_D_E_X



E_X_H_I_B_I_T_S

THE CLERK: All rise.
THE COURT: All right.
Everyone be seated.
All right. Everyone, good morning.
We have another witness on the stand.
Good morning.
MR. CONDE: Good morning.
Two quick housekeeping matters, the long awaited Temporary Restraining Order language.
THE COURT: Yes.
MR. CONDE: And also yesterday, during Dr. Elder's cross we marked up some images, and we've taken the originals and put stickers on the back and identified them as Defendant's Exhibit 468 A and 469 A, and I also have some additional copies.
THE COURT: All right.
Has counsel seen --
MR. CONDE: I've given a copy to counsel as well.
MR. SHATZER: I have, Your Honor.
THE COURT: All right. Fine.
MR. CONDE: These are the originals.
THE CLERK: Okay.
MR. CONDE: I copies of the two sets.
THE COURT: Okay. I'll read it while you're going ahead.

MR. CONDE: Thank you, Your Honor.

And just so the record's clear, the stamps on those are on the back of the images.

THE COURT: These the ones from yesterday?

MR. CONDE: Yes, Your Honor, from Dr. Elder's cross-examination.

THE CLERK: I have the originals.

THE COURT: You have them, Gail?

All right. Thank you.

You have these?

THE CLERK: I have the originals.

THE COURT: These are extra copies.

THE CLERK: Yes.

THE COURT: Okay. Fine. Thank you.

Will you identify the witness, please.

MR. SHATZER: Your Honor, I had one minor point, the Court's admitted order yesterday noted Mylan had rested and we had just finished our infringement case, we still have the invalidity case. I just wanted the record to be clear on that.

THE COURT: No, no. That's fine. I understood.

But thank you for clarifying.

Please go ahead.

MR. SCHEFFEL: Morning, Your Honor.

THE COURT: The -- Impax is still on the

infringement case?

MR. WEISBLATT: Yes, Your Honor.

THE COURT: We're back to the invalidity. Good.

MR. SCHEFFEL: Morning, Your Honor.

Robert Scheffel on behalf of Impax Labs, and our next witness is going to Dr. Andre Sommer.

THE COURT: All right.

THE CLERK: Place your left-hand on the Bible, raise your right hand.

D R. A N D R E J. S O M M E R, sworn.

THE CLERK: Please state your full name and spell it for the record.

THE WITNESS: Andre Johanns Sommer, A-n-d-r-e, J-o-h-a-n-n-s, S-o-m-m-e-r.

THE CLERK: You may be seated, sir.

THE WITNESS: Thank you.

DIRECT EXAMINATION

BY MR. SCHEFFEL:

Q Morning, Dr. Sommer?

A Morning.

Q Can you briefly explain your educational background for the Court?

A Yes. I received a Bachelor of Science Degree in chemistry from Delaware Valley College in 1979.

I then received a Master of Science Degree in

physical chemistry from Lehigh University in 1981.

And then in 1985 I received a PhD in philosophy specializing in analytical chemistry from Lehigh in again 1985.

Q Where are you currently employed?

A I'm currently employed at Miami University as a professor of chemistry and biochemistry. And I'm also the Director of the Molecular Microspectroscopy Laboratory.

Q And how long have you been at Miami University?

A I've been at Miami since 1986.

Q And at Miami what does your research focus on?

A At Miami my research focuses on the development and characterization and application of molecular microspectroscopies for surface analysis and materials characterization.

Q And do you focus your work on any particular type of microspectroscopy techniques?

A Yes. In particular, infrared microspectroscopy and pertinent to this case attenuated internal reflection imaging or ATR-FTIR imaging spectroscopy.

Q And do you teach classes at Miami as well?

A Yes, I do.

Q What classes do you teach?

A So I teach general chemistry at the undergraduate level, and at the graduate level I teach microspectroscopy,

micro-molecular spectroscopy surface analysis methods and optical microspectroscopy.

Q And in addition to what you referred to as ATR-FTIR imaging, do you focus on any other techniques?

A Yes, I use scanning electron microspectroscopy coupled with internal energy dispersal spectroscopy and imaging.

Q And you earlier just mentioned the molecular microspectroscopy lab?

A Yes, the MML.

Q What did the -- does the MML do?

A The MML is a contract or research development lab where we help companies solve intractable problems. So we specifically we look at very, very small particles, either isolated or small spatial domains on much larger samples. With some of the instrument manufacturers we actually help them develop new instruments and new accessories.

Q And does the MML routinely handle small samples?

A Yes. We routinely handle isolated particles down to 10 microns in size.

Q You mentioned that you developed techniques.

Can you give the Court an example of a novel technique you invented?

A Yes, we co-developed the ATR-FTIR imaging method with Proctor & Gamble and later with Perkin Elmer.

Q And how long have you been focusing on your research on

ATR-FTIR imaging?

A Since 1985.

Q Have you published articles in the area of electro microspectroscopy.

A Yes, I have.

I've published 75 articles in New York, I have eight book chapters in roughly 180 publications or presentations in the field.

Q And do you have a slide that identifies some of the articles that are pertinent to your testimony in this case?

A Yes, I do.

Q Could you put up slide one, please.

A So, the pertinent articles in this case, you'll notice that in 1991 we published the very fundamental article on the spatial resolution that you can achieve in infrared microspectroscopy.

We later in 2001 published the seminal paper on the development of the ATR-FTIR imaging method.

We then applied that method to look at very, very small mineral inclusions in kidney biopsies and that was a paper in 2010.

And these papers here, this one and this one (indicating), we published in conjunction with the trace evidence analysis section of the Food and Drug Administration and those are specifically looking at

pharmaceutical compositions.

MR. SCHEFFEL: Will you put up the ITX 617.

BY MR. SCHEFFEL:

Q Do you recognize ITX 617?

A Yes, I do.

MR. CONDE: Excuse me, do you have a witness book? Thank you.

MR. SCHEFFEL: Your Honor, may I approach?

THE COURT: Please.

MR. SCHEFFEL: My apologies, Your Honor.

THE COURT: No, that's all right.

If you could give a copy to the clerk.

MR. SCHEFFEL: It's early for me.

BY MR. SCHEFFEL:

Q Dr. Sommer, do you recognize ITX 617?

A Yes.

This is the article that developed -- detailed the the development of the ATR-FTIR imaging method, and in this paper we looked at various materials, we looked at the surface of hair fibers to get chemical distribution and we also looked a single red blood cell.

MR. SCHEFFEL: Will you put up ITX 619.

BY MR. SCHEFFEL:

Q Dr. Sommer, do you recognizes ITX 619?

A Yes. This is the paper that we published with Indiana

University Medical School over in Indianapolis, and this is where we actually looked at very, very small mineral inclusions, actually the first start of formation of kidney stones, in order to kind of figure out why kidney stones actually form.

Q Do you recognize ITX 618, Dr. Sommer?

A Yes. This is where we did ATR-FTIR imaging to look at counterfeit pharmaceutical tablets, specifically to identify counterfeit materials in the core of the tablets.

Q Now, Doctor, in addition to your work at Miami, what other things do you do?

A Since 1995 I've been consulting with various companies.

Q So how long have you been focusing on electron microspectroscopy?

A Since 1981.

Q Have you ever testified as an expert witness at trial before?

A No, this is my first time.

Q And do you have a curriculum vitae that provides additional details of your educational and professional background?

A Yes, I do.

MR. SCHEFFEL: Can you put up ITX 638, please.

BY MR. SCHEFFEL:

Q Dr. Sommer, do you recognize that document?

A Yes, that is -- that is my curriculum vitae.

MR. SCHEFFEL: Your Honor, at this point I would like to offer the doctor as an expert in ATR, including ATR-FTIR imaging and SCM techniques.

MR. CONDE: No objection, Your Honor.

THE COURT: All right.

Without objection he's so qualified to testify.

BY MR. SCHEFFEL:

Q Dr. Sommer, can you briefly tell the Court what you were asked to consider in this case?

A Yes.

I was asked to look at the Impax delayed release seeds and determine the molecular or chemical distribution from the surface of the seed all the way into the core. In particular, I was asked to opine on whether there was a HPMC derived material enriched in talc in between the delayed release coating and the core.

Q And can you provide a brief summary of your opinions for the court?

A Yes, I can. I have a slide on that.

MR. SCHEFFEL: Put up the slide, please.

A So using ATR-FTIR imaging and scanning electron microspectroscopy with energy dispersive spectroscopic imaging, I found that the delayed release seeds and talc randomly distributed throughout a single layer. There is no

evidence of a talc region near the core, and there is no chemically different and topographically stabilising coat layer of some unspecified HPMCP derived material enriched in talc.

Q Dr. Sommer, in connection with your work in this case, did you review the patent in suit?

A Yes, I did.

Q Did you review the Court's claim construction in this case?

A Yes, I did.

Q And do your opinions take into account the Court's claim construction --

A Yes.

Q -- as made here?

A Yes, they do.

Q Let's discuss some of your opinions in more detail. What analytical methods did you elect to use in this case?

A I used ATR-FTIR imaging and I also used energy dispersive spectroscopy along with imaging.

Q And to your knowledge, did anyone else in this case utilize ATR-FTIR imaging?

A No, it's -- to my knowledge, no one else has used this method.

Q Did anyone else in this case use SCM EDS analysis?

A No one else used SCM EDS imaging.

Q In what form did you analyze the delayed release seeds?
A We looked at cross-sections of the delayed release seeds which enabled us to look at the composition from the surface of the bead to the core.
Q Now, did you consider Dr. Davies' testimony and testing in this case?
A Yes, I did.
Q And you were here when he testified. Correct?
A Yes, I was.
Q Dr. Sommer, why didn't you repeat Dr. Davies' washing analysis?
A Much of the work that we do in the laboratory is forensic in nature dealing with trace evidence. And we're taught as good analytical chemists and forensic scientists not too adulterate the samples.

I believe Dr. Davies' washing step does just that. In particular, if you look at the components in the delayed release coating, it's highly likely, because of their differential soluabilites, it's highly likely that some materials will be removed and other materials will remain.

Q Now, did you review Dr. Davies' SCM images that he produced in this case?
A Yes, I did.
Q Did you see any evidence in Dr. Davies' SCM images that informed your opinion to the washing step?

A Yes, I did.

THE COURT: Counsel, did I understand, I thought you said he was the only one that did the SCM in the case.

MR. SCHEFFEL: Your Honor, he said he was the only one who did SCM EDS analysis. It's a additional analysis I will briefly step through with Dr. Sommer.

THE COURT: Okay. I just wanted to be sure I understood.

MR. SCHEFFEL: Thank you.

BY MR. SCHEFFEL:

Q Dr. Sommer, could I turn to ITX 194 in your notebook.

A Okay.

Q Do you recognize ITX 194?

A Yes. This was the production materials from Dr. Davies.

Q Could I ask you to turn to ITX 700 in your notebook.

Do you recognize ITX 700?

A Yes, I do.

These appear to be the same images from doctor -- that were included in Dr. Davies' deposition or his expert report.

Q And the difference being that there are Davies numbers down on the bottom right corner?

A Yes.

Q Can you turn to ITX 194-036.

A Okay.

Q Dr. Sommer, do you recognize that image?
A Yes. This is one of Dr. Davies images of an unwashed bead.
Q And what characteristics of this image are of note?
A What I'd like to point out is that at the -- at the delayed release coat or interface, or at the edge of the actual bead itself, you see that it's very smooth and there are no defects whatsoever.
Q Now, can we turn to ITX 194-005.
A Okay.
Q Dr. Sommer, do you recognize that image?
A Yes. This is the image of a bead that had been exposed to the 20 minute washing.
Q Is it your understanding that this image correspond to SCM 10 from Dr. Davies' report?
A Yes, it does.
Q And that's also referred to as PTX 231?
A Yes.
MR. CONDE: Excuse me, what is that image, 0055?
MR. SCHEFFEL: 005.
MR. CONDE: I apologize. I couldn't hear. I thought you said 55.
BY MR. SCHEFFEL:
Q And, Dr. Sommer, what characteristics of this image are of note to you?

A Well, now it's zoomed out.

MR. SCHEFFEL: Eric, can you please go back to ITX 194-005.

A So in particular, again, if you focus your attention to the coating or the area where the delayed release coat hits the core all the way around the bead, you can see significant cratering. So here and all the way through here.

Q Dr. Sommer, is that just an artifact of that particular seed?

A No. It wouldn't be an artifact of that particular seed because you don't see that throughout the entire seed itself. You only see it at the edge of the seed. And more importantly, the defects run parallel with the delayed release coat.

Q And to what do you distribute that to?

A I attribute that to the effect of using the acetone wash in preparation.

Q And do you have additional images in that ITX 194 that highlight this effect?

A Yes, I do.

Q Could you point to 194-004.

Do you recognize this image?

A Yes, I do.

This is a blow-up of the region of the previous

image.
Q And what does this image show to you?
A And, again, here you can see right along the delayed release coating or interface, you can see significant cratering along that interface.
Q Dr. Sommer, did you see similar evidence in any of the SCMs of any of the unwashed beads?
A No. The unwashed beads, again, they were characteristic for the first image that we showed, where he had a smooth surface at the delayed release coat interface.
Q Did you see any evidence of this cratering in any of the other SCMs of the 10-minute and five minute wash?
A Yes. There was evidence for the cratering but to a lesser extent.
THE COURT: Look at Exhibit 194. Isn't there cratering in that exhibit? And that's prior to being washed.
MR. SCHEFFEL: I'm sorry 194, what page, Your? Honor.
THE COURT: 194, the first image on line 4. Just kind of find it -- would you bring up 194-001.
MR. SCHEFFEL: Make sure we have the right image, Your Honor. Is this the image you're referring to?
THE COURT: Yes.
And to the left of the outer coating, isn't that

cratering?

THE WITNESS: Are you referring to this area up here, Your Honor?

THE COURT: Yes. All those dark spots. Right. Isn't that cratering as well?

MR. SCHEFFEL: That is a washed bead.

THE COURT: Is that a washed bead?

Okay.

The first one is a washed bead.

MR. SCHEFFEL: Yes.

THE COURT: All right. Fine.

Go ahead.

BY MR. SCHEFFEL:

Q Dr. Sommer, I'd now like to turn to the ATR-FTIR imaging, and in particular I'd like you to start with the description of the ATR method that Dr. Davies' utilized.

Can you please provide us with a brief description of the ATR-FTIR method used by Dr. Davies?

A Yes. I have a slide that shows the method.

So, in Dr. Davies' method, again, as he said, you point an I-R source into a material of high refractive index, in this case silicon. The infrared light then slightly penetrates out of the IRE and interacts with the the sample, and then the light that's reflected goes up. And in Dr. Davies case to a single detector.

When he records the spectrum, he gets a single spectrum over here. Now, Dr. Davies did this and he recorded a spectrum from a single 50 by 50 micrometer area on the surface of the bead.

So what you're looking at is material just on the surface, again, this penetration depth here is only one micron, and the spectrum that he records is a composite or mixture spectrum from that area.

Q And does Dr. Davies have to apply pressure to the interface?

A Yes, he does. He has to apply pressure in order to maintain intimate contact with the pellet and the actual IRE.

Q Now, let's talk about the ATR and SCM imaging analysis you did in this case.

A Okay.

Q Can you please provide the Court with a brief summary of ATR-FTIR imaging?

A Again, as I note here, we bring an infrared source in, in this case we have a **germane internal reflection element and that gives us a four fold improvement in the spatial resolution that we obtain. And as you'll note here, we're actually analyzing the cross-section bead so we can interrogate the seed from the surface to the core of the pellet.

And the other big difference is that in this case we have an array detector, so what we do is we select 16,384 spectra. Those spectra then are assembled into an image and we can chemically tune that image to any specific chemical component we're interested in. And you note over here we sampled a 200 by 200 micron area at two different spots, basically going from the surface of the bead into the core again.

And if you kind of take a look and look at this as a clock, you know, that each one of these squares will correspond to a number and so you know there are 12 hours in a day, if we divide one by 12, that shows that in this particular case we're sampling about 8 percent of the delayed release coat around the bead. And if we do two spots, we're up at around 16 percent.

Q Did Dr. Davies do any ATR-FTIR analysis all the way around the bead?

A No, he did not.

Q Dr. Sommer, can you briefly describe for us what the advantages of your method are over Dr. Davies' ATR-FTIR method?

A Yes, I can. I have several slides.

So what we're comparing on this slide is Dr. Davies' method on the left, and our method on the right. And again, if you look at Dr. Davies' method, he recorded a

single spectrum over a 50 by 50 micrometer area. And let's say you have two different components in that area, X and Y. The spectrum that he records is a mixture of those two materials.

So the important thing here is that what Dr. Davies would have to do is he'd have to actually go in then and interpret the spectrum. And in addition, you don't really know where, what the spatial distribution of X and Y is.

In our method, because we have such a very small focused spot at the sample, and we collect many many different, or 16,384 spectra, we have the ability to focus in almost on single components. And so the spectra that we record are going to be nearly pure components for the materials under study.

So in this case this is the spectrum of X, which for demonstration purchases is HPMCP, and this is the spectrum of Y, which is the spectrum of talc.

Q And, Dr. Sommer, can I have you now focus on another very important difference between your ATR-FTIR method and Dr. Davies analysis.

A Yes.

Q The depth analysis.

A Yes. That's shown in the next slide.

So here what we're doing is we're comparing the depth analysis between the two methods. So if you look at

-- we have four columns here. We have the seed or the type of seed; we have the delayed release coating thickness, the percent of the sample that was actually sampled, and the percent of sample that was actually unexplored.

And so if you look at Davies' unwashed seed, he said that the delayed release coating was approximately 14 microns thick. He also said that the beam penetrates the sample to a depth of about one micron. So this dark region here is his sampling area.

And then if you look over here, basically, he's has 93 percent of the sample that he's unexplored. So he can't tell what the composition is down in this region.

If you go to the washed seed, again, he mentioned that the remaining material was about four to six microns in thickness, so we have a sampling depth of again, one micron. And over here that corresponds to less than 25 percent of the delayed release coating that was actually sampled. 75 percent of that was unexplored.

Now, because we looked at cross-sections, okay, again, we're able to go from the surface of the seed all the way into the core. And because of our area, okay, we sampled a hundred percent of that area, again from the surface of the seed to the core, and the amount of material or area that was unexplored is zero.

Q And just to be clear, we're talking about the depth from

the surface all the way to the core. Right?
A Yes.
Q So does Dr. Davies know anything about the area right at the core interface chemically?
A No, he does not. There's no way with his sampling method he could have looked at that.
Q Now, earlier you said you were a co-developer of this technique. Right?
A Yes, I did.
Q And you understand its advantages and limitations?
A Yes, I do.
Q Based on your, I think you said 17 years worth of experience with this technique, do you think it has appropriate resolution to analyze the Impax delayed release seeds?
A Yes, I do.
Q Dr. Sommer, is your ATR-FTIR imaging technique accepted by others in the field?
A Yes, it's a relatively new technique, but it's widely accepted in the analytical science.
Q Do people come to you to learn about ATR-FTIR imaging?
A Yes. We've had many people to come to us to learn about the method and apply it in different situations including Los Alamos National Laboratories.
Q Turning a little bit to your sample preparation and your

analysis now.

Dr. Sommer, did you receive samples from Impax for analysis?

A Yes, I do -- yes, I did.

Q How did you isolate the delayed release seeds.

A We removed the seeds from the sealed bottle, we pulled out several of the tablets, and we gently crushed them in a bar pestil and what that did was to release the seeds from the actual tablet itself. We further isolated the seeds with a fine pointed probe and a tweezers under stereomicroscope observation.

Q And after you isolated the delayed release seeds, what did you do?

A What we did is we took those seeds over to the Center for Advanced Microscopy and Imaging at Miami University and we had them cross-sectioned under my supervision.

Q Why did you take the seeds there?

A Folks over at the center have wide experience in cross-sectioning a wide variety of different materials.

Q And you have a lot of experience with that lab?

A Yes, I do. That's where we do, actually do all of our high end sectioning.

Q And what is your level of confidence in the cross-sections that were prepared for analysis in this case?

A Again, many of the people over there have significant

years of experience, in particular Matt Gooley, who did the sectioning for us, has close to 15 years of experience, and so I have a very high degree of confidence with those people.

Q Dr. Sommer, do you have experience in analyzing layers of various materials?

A Yes, I do.

As a graduate student we looked at corrosion of car bodies, so there we were looking at the corrosion between the steel substrate and organic overcoat. So we were very interested in the interface. With our work in determining disease states, we look at very small particles and layers in cells and also our work with Kodak, we're looking at photographic film where the layers are very, very thin. So we have extensive experience in these types of samples.

Q And this isn't the first time that you've looked at pharmaceutical tablets. Right?

A No, it is not.

Q Is this the first time you've looked at cross-sections of pharmaceutical tablets in order to identify the sub layers?

A It's the first time we tried to or looked at pharmaceutical tablets to try to identify sub layers. But all of our other experience is applicable to this problem.

Q Now, was there anything special about the dosage form in

this case that posed any special challenges in your opinion?
A No.
Q And once the samples were prepared, what did you do?
A Once the samples were prepared, we did ATR-FTIR imaging, I believe it was on five pellets, at two different spots, and then we corroborated that data with scanning electron microscopy, inter-energy dispersal of microspectroscopic imaging, and we did that on three individual pellets.
Q I think you testified earlier you also conducted SCM EDS analysis. Is that right?
A Oh, can you repeat the question, Robert.
Q I think you testified you also conducted SCM EDS analysis. Is that correct?
A Yes, I did.
Q How many seeds did you analyze?
A The SCM EDS analysis, we looked, I think it was at one seed, but the SCM EDS imaging analysis we did on three sides.
Q Dr. Sommer, in conjunction with that analysis, what chemical entities did you focus on?
A Because Dr. Davies contends that there is HPMCP derived material enriched in talc between the delayed release coating and the core, we focused our attention on HPMCP and talc.
Q And did you include the images that you generated in

this case in your expert report?
A Yes, I did.
Q Could I point you to ITX 441 in your notebook, please.
A Okay.
Q You recognize ITX 441?
A Yes, I do.
This is a compilation of the optical and ATR-FTIR imaging results.
Q And did you also provide all the underlying data you compiled from your analyses?
A Yes, I did.
Q And did this include all of the thousands of I-R spectra that you generated in conjunction with your analysis?
A Yes.
Q You have -- you selected samples of images that you've created through your analysis to present to the Court today?
A Yes, I did.
Q I believe this is pellet three in the first location.
Dr. Sommer, can you briefly explain to the Court what these images represent?
A Yes.
What these are are ATR-FTIR images of the seeds and as you'll note in both of these images, we're going from the delayed release coating, which is depicted here -- I'm waiting for the Judge to find --

THE COURT: I have it. Thank you.

A Okay. The delayed release coating which is here, and over here (indicating), and this is the core, and in the left hand image we have chemically tuned that image to HPMCP using the 1722 infrared peak for that material.

Q And how are the colors assigned on these images?

A The colors are assigned by the computer in the software that's supplied with the instrument.

Q And what spectral resolution is this image taken at?

A We collected our images at four wave number spectral resolution, and the significance of that is that we can differentiate two chemically very similar materials using that resolution.

Q Were all of your images taken with four wave number resolution?

A We took some with four wave number resolution to get better definition, and others we took with eight wave resolution. But either one doesn't really make a difference.

Q Now, let's go to the image on the right back on 431-10.

Dr. Sommer, what does this image depict?

A So what this image is depicting is the image where we tuned to a specific or characteristic absorption or infrared peak for talc. And so what you're looking at here, again, we have the core over here. Here we have the delayed

release coating, and you can visualize the talc as the red yellow spots in that delayed release coating.

Q And what does that image show to you as an expert?

A As an expert it shows me that the talc is randomly distributed throughout the delayed release coating.

Q Dr. Sommer, how do you know that those red and yellow spots are talc?

A Well, part of the image is the fact that we have 16,384 spectra, and I can go in with my computer and pull out a single spectrum at a specific locations.

MR. CONDE: Objection, Your Honor.

None of these spectrum were provided to us during discovery. He's talking about spectrum he can go pull out, but none of them were provided to us during discovery, and I think he testified as much during the deposition.

THE COURT: Are you talking about -- that's a blow-up of 431-10. Right?

MR. SCHEFFEL: That's correct.

THE COURT: All right.

And these were not provided to you?

MR. CONDE: What wasn't provided was the spectrum he just referred to, he can pull out spectrum from his computer. But we never got those spectrum. That's my point.

THE COURT: All right.

Go ahead, counsel.

MR. SCHEFFEL: Well, that is incorrect, Your Honor. We provided all of the data files that have all the individual spectrum that he collected, all 16,000 of those, and all you have to do is open them up and you can pick on each one and the spectrum is there. So they did have that information from the beginning, at the outset.

THE COURT: All right.

The objection is overruled.

Go ahead.

BY MR. SCHEFFEL:

Q Dr. Sommer, do you have a slide to help explain the talc specificity?

A Yes, I do.

So again, you know, I have 16,384 spectra, and what I can do is that's what's made the image up, and I can go to a specific spot and pull the spectrum out and then I can interpret it.

So if we look at the red area, okay, I can pull a spectrum out there and the spectrum is color-coded to the color code of the image, and what you're seeing here is the infrared spectrum of talc. You can see the band at 1008 and you can also see the band that Dr. Davies identified up here about 3700 wave numbers as well.

If I go to the green areas in the delayed release

coating, again, I can pull a spectrum out, and again, what you notice here is that in this particular case we again have talc. And we're also starting to see a little bit of HPMCP which is down here at 1317-22.

Likewise, if I go to the aqua areas you can see the spectrum there, and again you note the feature at 1008, which is characteristic for talc, and again a little more HPMCP.

Q Dr. Sommer, why did you pick the 1008 peak for talc?

A The 1008 peak for talc is very characteristic for that material and it's also a very strongly absorbing peak.

Q Now, you heard Dr. Davies criticize you for picking this peak because in his opinion the talc band overlaps the HPMCP? Is that correct?

A That is correct.

A Do you agree with Dr. Davies?

A No, I do not.

Q Why not?

A I have a slide that shows that.

MR. SCHEFFEL: Slide eight, please.

BY MR. SCHEFFEL:

Q Can you briefly explain to the Court what this slide is?

A So, this slide is our spectra that we provided during my expert report, you can sigh the source down here.

Q Those sources, just for the ITX, are 402 and ITX 403?

A Okay.
Q And what you're seeing is the blue spectrum is the HPMCP and the black spectra is the talc. So here you see the 1008 wave number band, and then if you look at the HPMCP, you have a band at 1063 here, and a band at 947. So, roughly, we've got a 40 wave number difference here, and roughly a 50 wave difference number here.

So now our spectral resolution are -- was four wave numbers and, you know, these bands are this far apart. (Indicating). So we can easily distinguish those bands based on spectral resolution.

More importantly, if you look at the absorption strength of talc, in this -- these plots, we've plotted these on scale, and the spectra were recorded under identical conditions. And so what you see is that the talc is significantly more absorbing, or in this case it's 7.35 times more absorbing. So when you looked at delayed release coating you're really looking at talc because of the intensity.

Q So based on your experience, this 1008 wave number peak that you picked, is that specific for talc?
A That is specific for talc.

So both of the -- both of these facts that we have enough spectral resolution and the intensity differences, both of those facts say that yes, the images that we're

seeing are definitely talc.

Q Now, Dr. Sommer, you also heard Dr. Davies criticize the spatial resolution of your method. Is that right?

A Yes, I did.

Q Do you agree with that criticism?

A No, I do not.

Q Dr. Sommer, what is the spatial resolution of your ATR-FTIR imaging method?

A The spatial resolution of the method is one half the wavelength of light that you're using for analysis.

So, for example, at the 1722 wave number position for HPMCP, the wavelength is 5.8 micrometers, and if you take up half of that, we wind up with something slightly less than three micrometers.

If you look at the 1008 wave number feature for talc, the wavelength for that is 9.9 micrometers, and if you take half of that wavelength, it's slightly less than five micrometers.

Q I'll have you turn to, in your notebook, to PTX 250, please.

A Is that PTX 250?

Q PTX 250. Correct.

A It's in the back. Okay.

Q Do you recognize that document?

A Yes.

This is a technical note that Perkin Elmer Corporation, the folks that co-developed the method with us, published on the spatial resolution of the ATR-FTIR imaging approach, and in these technical notes verifies experimentally the spatial resolution that we're contending.

Q Dr. Sommer, did your method have sufficient resolution to analyze and determine whether there is as intermediate layer as Dr. Davies suggests?

A Yes. And I believe I have a demonstrative for that.

Q Slide to help explain?

A Yeah.

MR. SCHEFFEL: Can you please.

A So again, what you're seeing here is a blow-up of the region from pellet three. Here we have a delayed release coating from here to here, and what I've done is again, using the software provided with the instrument, I drew a line, and that line has a distance of 20 micrometers. And so you can see these three entities here as separate entities, and if you envision, I can put another one over here, and I can put another one over here, so I basically have a 20 micrometer distance divided by five. So I I have spatial resolution of four micrometers.

Q And were you here when Dr. Davies testified as what he said is a stabilizing layer, a single layer?

A Yes, I did, or yes, I was.

Q Does your technique on the spatial resolution detect a single layer of between four and six microns?
A So if there were two layers there, and they were separated by five microns, I would be able to distinguish those two layers. If there's a single layer present, and I only needed to detect that single layer, I could detect that single layer, even if it was less than one micron thick. Again, because talc is very, very strong infrared absorbent.
Q Dr. Sommer, did you see any evidence of a layer as Dr. Davies suggests in your analysis?
A No, I did not. Not in the context that he used where it was talc enriched HPMCP modified.
Q Now, can we move to HPMCP, can we go back to 436-10, like to focus on the image on the left.
Dr. Sommer, what does that image show?
A Again, this is an image that has been tuned specifically for HPMCP using the 1722 infrared peak. And again, what you're looking at here is the core, and over here the red and yellow areas are areas where the HPMCP is high in concentration and the green areas are where HPMCP is relatively low in concentration.
Q Did you sey HPMC?
A HPMCP, right.
Q Sorry.
Now, what are the green bands?

A Okay.
Q Do you see those?
A So you see this green band here, and you'll note there's also a green band over here. And these regions are where the HPMCP, sorry, John, is beginning to mix with the core, and then likewise out here, this is where HPMCP is beginning to mix with the area, because again we're looking a very sharp interface.
Q Are those green bands any evidence of an enrichment?
A No, they are not.
Q Dr. Sommer, if their HPMCP material is chemically different from HPMC, would your ATR-FTIR imaging method detect it?
A No, it did not.
Q I said, could it defect?
A Oh, I'm sorry. Could it detect it? Yes, it could.
THE COURT: What does the yellow represent, Doctor?
THE WITNESS: The yellow is areas where the HPMCP has a reduced concentration, so it, again, the HPMCP is highest in concentration, you can see the orb bends over here, yellow, lower in concentration, and then green, still lower in concentration.
THE COURT: Okay. Thank you.
BY MR. SCHEFFEL:
Q Now, Dr. Sommer, just to follow-up on that.

If there were a HPMCP derived material, what would you expect to see in your analysis?

A If there were a HPMCP derived material I would expect to see an additional infrared peaks in the spectra, or I would expect to see a slight shift in the existing peaks, and Dr. Davies in his data has shown neither.

Q And just to be clear, did you see any evidence of that HPMCP derivative in your analysis?

A No, I did not.

Q Now, did you see any evidence of band shifts in Dr. Davies I-R data?

A Yes. In Dr. Davies data we noticed a downshift of about three wave numbers and through computer modeling --

MR. CONDE: Your Honor, none of this, he mentions the band shift in his expert report, but it doesn't mention the computer modeling that he's about to talk about in his expert report. He doesn't identify the band shift, doesn't say how big the band shift is, none of this was in his expert report.

MR. SCHEFFEL: Your Honor, it was discussed in his expert report, and it was gone into in extensive detail in his deposition as well.

MR. CONDE: Your Honor, I'd be happy to show you the paragraph where it's in his expert report, referred to it. It doesn't go into any detail.

THE COURT: I'm going to allow it.

Go ahead. Overruled.

A So the band shift that we noticed, again, the band for HPMCP I believe in Dr. Davies data showed up at around 1725. And there was a three wave number shift down.

And so what we did is we took our reference spectra and we did computer modeling and we showed that even with 5 percent by weight acetone in that material, or in that mixture, the band shifted down to almost where Dr. Davies observed the band in his data. And so what that indicated to us, it was strong evidence that there was still acetone remaining in the coating when he actually did this analysis.

Q Now, what did Dr. Davies say about this band shift?

A In Dr. Davies data he identified that specific band shift as just HPMC or HPMCP.

Q So either way, through testimony or Dr. Davies' data, is there any evidence of a HPMCP derived material?

A No, there is not.

Q Dr. Sommer, I'd just like too quickly step through some of the additional witnesses in 441, just to show the representative work you did. I don't want, for all the Court's time and everyone else, belabor these, but can you -- can I have you turn to 431. And this is pellet three, location two?

A Yes.

Q Dr. Sommer, are these images consistent with your prior opinions concerning the presence and location of talc and HPMCP?
A Yes, they are.
Q Can I have you turn to 431-003. And this is pellet one in the first location. And this is I believe an eight wave number image?
A Yes.
Q Are those images consistent with your prior opinions concerning the presence and location of talc and HPMCP?
A Yes, it is.
Q Can we go to 431-005. And this is pellet one in the second location.

Dr. Sommer, are these images consistent with your prior opinions concerning the presence and location of talc and HPMCP?
A Yes, they are.
Q I'm going to have you go to 431-01. This is pellet five at the first location at four wave numbers.

Dr. Sommer is this -- are these images consistent with your prior opinions concerning the presence and location of talc and HPMCP?
A Yes, they are.
Q And just to go to one more, I'd like to go to 431-015. And this is pellet five at the second location?

A That is correct.
Q Dr. Sommer, what is this set of images?
A This, again, is -- these are the images for HPMCP and talc.
Q Dr. Sommer, why does the coating in these images appear so much larger than the other images?
A Again, as I noted earlier in the description of the method, we have to apply a little bit of pressure to the sample to get intimate contact, and in this particular case we applied a little bit too much pressure, and so the coating being 20 microns in width, it flattened itself out to about 50 microns in width.
Q And why did you include this image in your report?
A I included it to -- for completeness of the record.
Q Does this image change your overall opinion?
A No, it does not.
Q I'd briefly like to focus a little bit on Dr. Davies' I-R spectra.
MR. SCHEFFEL: Can you pull up ITX 221.
BY MR. SCHEFFEL:
Q Do you recognize that exhibit?
A Yes, I do.
Q Now, you were here when Dr. Davies testified that in his opinion the I-R spectra here were chemically different. Right?

A That is correct.
Q Do you agree?
A No, I do not.
Q Why not?
A Again, Dr. Davies himself identifies this particular peak as HP 50. And if you do a close analysis of the spectra, there are no additional features, and we didn't notice any band shifting other than what we mentioned earlier.
Q So in your opinion, do these I-R spectra reflect a chemical difference?
A No, they do not.
Q Dr. Sommer, I'd like to turn now to the SCM EDS testing that you conducted and you were here when Dr. Davies discussed this analysis. Right?
A Yes, I was.
Q And he said that your data was not substantially different from what he found in the SCM images. Right?
A That is correct.
Q Do you agree with that?
A No, I do not.
Q Why not?
A Because our SCM EDS analysis differs significantly in two different ways.
We took the extra step of doing the energy

dispersive spectroscopic imaging which identifies or can look at an individual element in talc, and in addition to that, we were able to identify the exact spatial location for those talc particles.

Q Did Dr. Davies conduct any EDS analysis?

A No, he did not.

Q Did you hear any reason why he did not conduct such analysis?

A No, I did not.

Q And can you briefly describe for the Court what an EDS analysis is?

A Okay.

In EDS analysis or Energy Dispersive Spectroscopy, what you do is you bombard the sample with electrons, and the result of those electrons are that an electron from the sample in question is emitted from the core of the -- the core of the atom itself. And that electron is very characteristic for the element that you're looking at.

So, for example, we can differentiate between silicon and we can differentiate between magnesium. So the power of that method's very similar to infrared. In infrared we can -- we collect spectra, and those spectra are unique fingerprints for the molecule. In energy dispersive spectroscopy the spectra that we collect is a very unique fingerprint for that particular atom. Again, like infrared,

we collect thousands of spectra over a broad area, and then we can re-assemble those spectra into atomic specific or element specific image.

Q Okay.

Why did you opt to do that type of analysis?

A Again, that type of analysis, EDS, gives us a little bit better differentiation. EDS spectroscopic imaging gave us another method to look at also to corroborate our ATR-FTIR imaging results.

Q Did you look at the cross-sections of the beads in conjunction with this analysis? Correct?

A Yes, I did.

Q Now, can I have you turn in your notebook to ITX 643, please.

Do you recognize ITX 643?

A Yes. This is a compilation of the SCM EDS analysis data that I did.

Q Dr. Sommer, can you briefly describe what is shown up here in ITX 643-3?

A Okay. This is -- what you see up here in the left hand corner is a back-scattered image of the actual sample. And then, if you -- if you go back to the full view, what we've done over here is we have mapped the same image for magnesium, the same image for silicon, and for chlorine, and if you look at the magnesium image, we've colored the

locations where magnesium is present in blue.
Q Why did you pick magnesium?
A Again, magnesium is one of the elements that's present in talc. Likewise, silicon is present in talc.
Q So the images on the right side of this figure represent the distribution of talc?
A Yes. Well, the distribution of magnesium from which you can get the distribution of talc.
Q A representative. Is that correct?
A Yes.
Q And, Dr. Sommer, if I can have you go back to the back-scattered image.
Can you point to us where the delayed release layer is?
A Yes. The delayed release is right along here. Okay. So you can see the interface here with the core. And the delayed release layer kind of ends there and then you can see individual talc particles over here.
Q And where is the core?
A The core material is down -- all down here.
Q Now, Dr. Davies criticized your images because of the upper right corner up there. Right?
A That is correct.
Q What is that area in the upper right corner?
A The upper right corner is where you have, because of the

topology of the actual seed itself, that could be where you have a dimple or where the bead actually rolls off, kind of like an over the horizon view. However, I would like to note that in many of Dr. Davies SCM images you see the same effect.

Q If I can have you turn to ITX 643-009, please.

And what are these images?

A Again, these are the back-scattered images for the sample. You're looking at the magnesium map and the silicon map and the chlorine map, and what's really neat about these images are that you can actually see the delayed release coating here. Okay.

I have much better detail now. So you can see the delayed release coating which is right here and here. And you can see the actual individual talc particles now. And if I do my elemental imaging, you know, we can go back and look at the magnesium image.

Okay. What I've done in this case is I've overlaid the elemental map with the back-scattered image and now you can see the individual talc particles highlighted in blue.

Q And what do you conclude from that image with respect to talc?

A Again, from this image, with respect to talc, the talc is randomly distributed throughout the delayed release coating.

Q Now, if you -- if we go back to the full view of this page, focus your attention down at the bottom of that. I believe you were here when Dr. Davies criticized these images because of the pink region up in the middle of the page on the right?
A That is correct.
Q What is that?
A That is a chlorine containing material.
Q Is that typically present in the outer coating?
A No, it is not.
Q Did you see this in any of the other SCM EDS analysis?
A No, I did not.
Q Does this in any way effect your opinions?
A No, it does not.
Q Now, you were also here where Dr. Davies criticized your EDS analysis because he said your sampling depth is up to five microns. You remember that?
A Yes, I do.
Q Do you agree with that?
A No, I do not.
Q Why not?
A That is a misleading statement.
What Dr. Davies was considering was that he was looking at the penetration depth or the depth at which the electrons go for HPMCP. The images that we generated for

magnesium, the electrons come specifically from magnesium, nothing else. They don't come from HPMCP, they don't come from magnesium or silicon. And if you calculate the penetration, that number comes out to be 2.1 microns.

Q And just to sum up, Dr. Sommer, can you please provide the Court with an overall summary of your opinions based on your analysis in this case?

A Yes.

Based on my analysis using ATR-FTIR imaging and energy dispersive spectroscopic imaging, I found that the talc in the delayed release coating was randomly distributed. Further, I see no evidence for an HPMCP derived material enriched in talc located between the delayed release coating and the core.

Q And do you have any conclusion as to whether the Impax seeds contain a stablizing coat and the core and the delayed release coating?

A Yes. The Impax seeds do not contain a stablizing coat between the delayed release coat and the core.

Q Thank you.

A Thank you.

THE COURT: All right.

Thank you, Mr. Scheffel.

CROSS-EXAMINATION

BY MR. CONDE:

Q Good morning, Dr. Sommer.
A Good morning.
Q Let's discuss your experience briefly again, just so that we're clear.

I think you testified this morning that you've only offered two papers regarding pharmaceutical preparations. Right?
A That is correct.
Q And both of those were looking at the core materials, not at a layer. Right?
A That is correct.

But through my extensive experience with other materials, again, I cited those in my testimony today.
Q And you're not an expert regarding coatings used in pharmaceutical formulations, are you?
A I'm an expert in coatings and organic coatings in general, used for coatings on car bodies, coatings on polymer films, so I view myself as an expert in those areas.
Q Turn to your deposition, sir, page 73.
A Yes. Okay.
Q Were you asked the question, "are you an expert on coatings used in pharmaceutical formulations?

"Answer: I'm not an expert in coatings used in pharmaceutical formulations but I can be considered a expert on coatings."

Were you asked that question and did you give that answer?

MR. SCHEFFEL: Objection, Your Honor. That's not a question --

THE COURT: Is there any significant difference in analyzing pharmaceutical coatings and analyzing some other sample for coatings?

THE WITNESS: No, there is not.

THE COURT: Okay.

BY MR. CONDE:

Q Well, some of the things you do analyze are paints. Right?

A Yes.

Q And they contain organic coatings very similar to HPMCP, and you wouldn't swallow paint though. Right?

THE COURT: Oh, come on, Mr. Conde.

MR. CONDE: Well, I think there's a difference --

THE COURT: You can think there's a difference, but I didn't hear there's a difference. I mean if you apply the same kind of analysis and you put the sample under the same kind of testing, if it's there, it's there, I would assume. Is that correct?

THE WITNESS: Yes, that's correct.

BY MR. CONDE:

Q Are you an expert in institute coat formulations,

Doctor?
A No, I am not.
Q And you --
THE COURT: Do we have any expert in institute formulatons?
MR. CONDE: Dr. Davies is. He testified in his other previous cases --
THE COURT: But he didn't know how in this case an NC 2 layer may have formed. Did he offer any testimony about that?
MR. CONDE: No, he didn't, Your Honor.
THE COURT: Okay.
BY MR. CONDE:
Q And with regard to your technique, you thought it was appropriate to apply under this circumstance even though as far as you knew no one else had applied your technique to pharmaceutical preparations. Right?
A Again, when we applied the technique we had experience with other materials and samples that had a similar structure.
Q Let's talk about your SCM data. I just want to make it clear.
You did not do any SCM data on washed beads. Right?
A No, I did not do any SCM data on washed beads.

Q Okay.

So, could you please turn to your exhibit book first and go to ITX 194.

Q And at ITX 194 are a series of images from Dr. Davies work. Correct?

A That is correct.

Q Okay.

So they're not identified on it, the identity of the pellet or the sample is not provided anywhere on any of these images. Right?

A Yes, I believe so.

Q You believe -- you believe that there's no identification of a precise pellets on any of these pages?

A Yes, I do, or I believe that there's no identification.

Q There's no identification?

A Yes.

Q So from looking at this set of images, it doesn't identify whether any of them are washed or unwashed, does it?

A No, it does not.

Q So if you could turn to 194 015. From looking at the image you wouldn't know whether it's washed or unwashed. Right, Dr. Sommer?

A It's a relatively low magnification, but just looking at the characteristics of the bead I believe that this specific

bead, the 194 015 is an unwashed bead.
Q Now -- but you would want to confirm that based on an index that was given to you. Right?
A Well, what I was -- what I would want to do is I would want to look closer at the delayed release coating core interface.
Q Well, how about the image before that, which is 014. Do you know if that's washed or unwashed?
A Again, this is a small section now, so we'd have to go to something intermediate to look to see whether it was washed or unwashed. Now, looking up --
Q Well --
A -- looking up -- looking up in the upper left hand corner, it does appear that this is a washed bead.
Q Okay.
Because in the left hand corner you see cratering?
A I see cratering.
Q All right.
And of course this is a two micron image, right? Two microns is the size of the image?
A That's the scale at the bottom, yes.
Q And I think you went to 194 004 and that's a two micron scale as well. Right?
A Excuse me, which image are you talking about?
Q 004.

A 194 00 -- 4. Yes. That's a two micron scale.
Q Okay.
So you believe that one, that 014, is a washed bead. Right?
A Yes. In the 194 004 that shows significant cratering, and so that's again the 20 minute washed bead. If I go back to what bead was it now?
Q 014.
A 014. Okay. Because there's only one section in this particular bead I would say, you know, that this would be a five minute wash.
Q Okay.
A If --
Q Okay.
So go back -- go to, in your book, ITX 700, and leave open the image from 014 and go to ITX 700 and turn to page 20267.
A Oh, ITX 700 to what?
Q 20267.
A 20267.
THE COURT: What book are you talking about?
MR. CONDE: In his book, it's ITX 700.
THE COURT: Right.
700. And then which?
MR. CONDE: Page 20267 of 7.

A 20267.
Q Is the image at 20267 a washed or an unwashed bead?
A Again, it appears in the upper left hand corner you have cratering in that region.
Q Now, go to ITX 669.
You have ITX 669?
A I'm getting there. Six -- 669 or 699?
Q I'm sorry, 699. Thank you.
And you know what this is, right, Dr. Sommer? It's an index that was provided for all of the Davies production numbers identifying whether the beads were washed or unwashed. Right?
A That is correct.
Q So let's look at page in the index, on the first page 20267. You see that?
A That is correct.
Q And it says it was an unwashed bead. Right?
A That's correct.
Q So there were, the unwashed beads have craters as well. Right?
A Does 20267 correspond to the image that we just looked at?
Q Yes, it does.
A So can you direct me to that image?
Q It's right in ITX 700.

A Yes, that is correct.
Q Now, Dr. Sommer, you agree that HPMCP is soluable in acetone and water. Right?
A What do you mean by "soluable"?
Q Do you agree that HPMC 50 is soluable in acetone and water?
A Well, I don't recall the conditions that were shown in Court this week regarding --
Q Okay.

Would you turn to your transcript, page 280, please. And start at line 9, and were you asked this question and did you give this answer.

"Question: What is your knowledge of the solubility of HPMCP in a mixture of acetone and water?" There was an objection, and then you give an answer, but I'm going to skip to about line 20, where you say "ethyl or triethyl citrate is an ester just like HPMCP. So both materials should be soluable in acetone."

Were you asked that question and did you give that answer, sir?

A Yes, I gave that answer, but later on I questioned, you know, there's a degree of solubility. So for HPMCP and TEC, sure, they might be soluable, but the question is to what extent. There has to be some quantitative information provided.

Q You didn't include any of that in your response in the answer at the deposition, did you, sir?
A I believe I did.
Q And you don't have any specific knowledge of what is required to remove HP 50 and talc coatings from pharmaceutical products, do you?
A No, I do not.
Q And I think what you said is that at one point you said that Professor Davies did not wash the beads long enough. Do you recall that, Dr. Sommer, there in your expert report or deposition?
A Can you show me specifically where?
Q Sure.

Go to page 286.

A Okay.
Q And on page 286 were you asked the following question and did you give the following answer.

"Question: If the thickness of the remaining layer does not change in a 10-minute wash versus a 20 minute wash, what does that say to you?

"That says, -- Answer: That says to me there is a point at which HPMCP solubility, because of -- there is just not enough time to actually do the dissolution."

Do you see that, sir?

A Again, this is on page 286?

Q Yes, sir. Yes.

You see that question and answer?

A And you're talking about line 23?

Q No, I'm at line 3 to line 11.

A Okay.

That is correct.

Q You didn't make any attempt to wash Impax's beads with acetone and water longer than 20 minutes, did you, sir?

A No, I did not. Because I feel that the acetone water wash contaminates and adulterates the seeds and in my analysis it wasn't required.

Q Okay.

So let's turn to your ATR-FTIR outlook work.

Now, if there are two different materials mixed together within your bead, you will get a different spectrum than either of the spectrum for the materials individually. Right?

A So, if you have two materials, two separate materials, and you take those spectra and then if you take a spectrum of the mixture, the spectrum of the mixture is going to be a result of not only the weight percent based on those two materials and the combination of those individual bands.

Q So when you're looking the at the area of a sample and the sample is a mixture of components, the spectrum that results from that area will be a mixture. Right?

A Yes, it will be a mixture spectrum.
Q So if both HPMCP and talc are in the same area you're looking at, the spectrum will show both. Right?
A Yes. But again, keep in mind that talc is significantly stronger in absorption strength than the HPMCP.
Q Now, you talked about Dr. Davies TIR testing. Right?
A That is correct.
Q And in your analysis, you did not take into consideration the properties of the surface of Impax's beads after it had been washed with acetone and water. Right?
A Again, I saw no need to actually wash the bead. We looked at the cross-sections as received and intact. We did not treat the beads chemically because that alters the bead.
Q The answer to the question is that my statement was correct. Right?
A The answer is that --
THE COURT: He answered the question. He answered the question. I'll accept the answer that I heard.
BY MR. CONDE:
Q Okay.
So let's go to ITX 431. I think that's in your book. And turn to page Sommer 316.
A ITX what again?
Q 431.
A 431.

Q Sommer 316.

Okay. So if you look at that page, on the left --

A I'm still --

Q -- you have imaging and you have another image corresponding to the same location on the right. Correct?

A Is this Sommer 316?

Q Yes.

A Well, the image up on the screen does not correspond to what's in the book.

Q There you go. It does. Right? On the right-hand side?

A Okay. Hold on -- hold on.

Q You see on the right-hand side it says, "Sommer 316"? Maybe you're just not in the right place.

A Sommer 316.

Yeah. The image that I have here doesn't correspond to that number.

THE COURT: Why don't you just refer to the images on the screen? That's what it's there for.

A Okay.

Q All right. Okay.

So the image on the left, the two images are in the same location. Correct, Dr. Sommer?

A That is correct.

Q And on the left you say that the image is HPMCP specific. Right?

A That is correct.
Q And you identify the peak 1722. Right?
A That is correct.
Q And you say that it's HPMCP specific because you were focused on this 1722 wavelength. Right?
A That is correct.
Q And THAT wavelength is distinct for HPMCP. Right?
A That is correct.
Q And on the right you have a wave number of -- well, let me start over. A wave number of 1008. Right?
A That is correct.
Q And then in brackets you say that that wave number is talc specific. Right?
A Yes.
Q And if you look at this image on the right, the green is supposed to designate the presence of talc. Right?
A That is correct.
Q So based on your image on the right, there's talc throughout the outer coating of the Impax pellet. Right?
A Well, what I said in my earlier description here is the green area here is where talc is mixed with HPMCP. So you have talc in a slightly lower concentration than the red and yellow areas.
Q But the whole layer that you've got on the screen where it's green, that's all designated talc. You don't

differentiate between where HPMCP is versus where talc is on the right panel of that image. Right?

A Well, again, the image is tuned for talc. So we're looking at the wave number for talc, 1008. Now I --

Q And -- and in that image you see some patches of red and yellow right on the right-hand corner, on the right hand panel you see red and yellow. Right?

A Yes, that's correct.

Q And you don't know what the relative amount of the signal that's coming from talc is as opposed to other ingredients from your mapping. Correct?

A I can go in and I can pull an individual spectrum out at any given location, and I can do a modeling experiment which would give me the concentrations.

Q You didn't do any of that experiment for this litigation, did you?

A No, I didn't need to.

Q Okay.

So could you turn to page 251 of your deposition, sir, and actually start at page -- yes, 251, line 24.

A 251, line 24. Okay.

Q Right.

And were you asked this question and did you give this answer.

"Question: And do you know the relative amount of

that signal that would be coming from talc?

"Answer: No."

And you go on, but I don't think you gave -- I'll go on and read the rest just for completeness. "Again, because I don't know -- I don't know in the analysis that we were requested to do, we were not asked to give quantitative analysis of material, all we were asked to do was to detect the presence of an enriched layer at the core, extended release coating interface, and we did not. All of our data shows that the layer does exist."

Were you -- were you asked that question and did you give that answer?

MR. SCHEFFEL: All right.

Your Honor, objection. I think he misread that. It does not say --

THE COURT: Mr. Scheffel.

MR. SCHEFFEL: Sorry, Your Honor.

MR. CONDE: It does -- it says the layer does not exist. I apologize if I misspoke.

A So I'm missing your point.

Q Could you please just answer my question.

Were you asked that question and did you give that answer?

A Well, could you repeat the question? Because I'm missing the point you're trying to make.

THE COURT: Go ahead, repeat the question and let's see.

BY MR. CONDE:

Q Okay.

The question, "do you know the relative amount of that signal that would be coming from talc?

"Answer: No."

Were you asked that question and did you give that answer?

THE COURT: Yes, he did.

THE WITNESS: Yes, I did.

THE COURT: If it's there you did.

THE WITNESS: But --

THE COURT: So now the next question.

BY MR. CONDE:

Q Okay.

Now can we just go to slide seven of Dr. Sommer's -- okay. I just want to clarify something. You didn't pull out and display any particular area of your Raman of your ATR-FTIR mapping that's displayed on the left there, you didn't pick out and display any of the individual spectra in your report. Right?

A In what?

Q Well, let me ask the question.

Where did this spectra come from, this image?

A That spectra came from this red dot there.
Q Okay.
And you didn't provide this spectrum on the right and identify that it came from that red dot there in your report, did you?
A I provided all 16,384 spectra in the files.
Q In your report you don't provide the spectrum on the right and identify any red dot on the left. Correct?
A In my report I identified the red dots as in the yellow areas as being talc.
Q Okay.
So let's talk about that a little more.
In the red and yellow areas you also see talc marked with HP 50. Right?
A The HPMCP, yes.
Q So even in these red and yellow areas for your image that's tuned for talc, it could have HPMCP in it as well. Right?
A Well, again, if you look at the spectrum here, you see talc bands and there's a little bump there for 1722. That's typical.
Q And so when you said talc specific in your expert report, you did not mean talc pure images. Right?
A The terminology that's used in the field is that when you're presenting these images you tune to a band

characteristic for the material. So you have a level of specificity, yes.

Q So could you go to slide five of your demonstratives, please. Could you go to that slide.

And on this slide you show two -- you show a grid of your work on the right. Right?

A That is correct.

Q And each box is 10 microns by 10 microns. Correct?

A That is not correct. This slide was just made for demonstration purposes.

Q Well, the slide, when you look at the grid, it's 10 microns by 10 microns for each box. Right?

A Well, I haven't counted the boxes, but in the real world at least, in the instrument, each one of these boxes is 1.6 by 1.6 micrometers in dimension.

Q So just so I'm clear, I don't want the nomenclature to get anyone confused, you're saying it's 1.6 microns by 1.6 microns?

A Yes.

If you take a pixel on the detector and trace it back to the sample position, at the sample position the detector shows up as a 1.6 by 1.6 micron spot.

Now, I said earlier that our spatial resolution is half the wavelength, which is a five micron spot.

So if you think about it, for each five micron spot

that we're looking at in the image, we're oversampling by a factor of three. We're actually doing an experiment three times, and that's the difference between pixel resolution and spectral resolution.

Q So just so we're all clear, on slide five of your demonstratives, when you have the grid for your experiment, that does not accurately portray the dimensions of each individual box. Right?

A No, it does not. Because if we would have tried to accurately portrayed it we couldn't have seen the boxes, the detail would have been too small.

Q Now -- now, you're aware that there's areas in your imaging where the talc overlaps the HPMCP signal. Right?

A Again, in my slide that I showed it's a moot point, because talc is seven and a half times stronger, infrared absorbing the signal that we see for talc is significantly higher than it is for HPMCP.

Q So, Dr. Sommer, there are areas on your images where you co-detect in the same location HP 50 or HPMCP and talc. Right?

A Yes.

But again, co-detect, you know, we've got talc, you know, okay, we're looking at the sun, that's the intensity of talc, and then we look at HPMCP, and that might be the intensity of the moon. And if you have those two together

you're going to see specifically talc.

Q Would you go to our slide number seven, please.

Okay. So on this slide we've got this is pellet one, first location, that was in your expert report. Right?

A That is correct.

Q And we carefully drew a box on the HPMCP image and we see red in that box. Right?

A That is correct.

Q And the red's designating HPMCP. Right?

A That's correct.

Q And if we look at the box to the right, we also see red in the box to the right at about the same locations as the box to the left. Right?

A That's correct.

Q So if you look at these locations, you can't tell at any particular location whether you're seeing only HPMCP or only seeing talc. Right?

A Well, again, what you have to consider in looking at these images here, you can see a negative of this particle here, this is HPMCP -- or this is the talc and this is a negative image. But one thing you have to consider is that that talc particle could be half a micron thick in depth. And so what you're actually doing is you're interrogating through the talc particle into the HPMCP.

THE COURT: Could I see your laser, please, Doctor?

THE WITNESS: Oh, sure.

THE COURT: This is an image of an unwashed bead. Correct?

THE WITNESS: Yes.

THE COURT: Unwashed pellet. Correct?

THE WITNESS: HPMCP.

THE COURT: And you made an observation through your ATR-FTIR examination. Correct?

THE WITNESS: Correct.

THE COURT: And in your observation did you make -- were you -- you testified to this, I just want to be sure I understand. Did you discern any noticeable differentiation in this area that would suggest to you that there's a layer within this area, a separate layer within this area?

THE WITNESS: No, I did not.

THE COURT: And this is the area, Mr. Conde, that Dr. Davies washed and did an examination of after the wash. Correct?

MR. CONDE: That's correct.

THE COURT: Okay.

And his testimony and opinion is that during the wash a portion of this layer was dissolved. Correct?

MR. CONDE: Yes, Your Honor.

THE COURT: And what was left, his opinion is, is the stabilizing layer. Correct?

MR. CONDE: Correct.

THE COURT: All right.

But this Doctor is testifying that in his examination, as he examined throughout this layer, he did not discern any noticeable differentiation or composition of the materials in that layer.

Is that correct, Doctor?

THE WITNESS: That is correct.

THE COURT: I don't think we need too much more time on this.

MR. CONDE: Okay.

THE COURT: I understand the issue.

MR. CONDE: Okay.

THE COURT: I mean you have a doctor who testified as to what he did, and he says what's left is a layer. This doctor is testifying he examined this area, and it's of the same composition throughout. So that's what the Judge is here for, eventually. You know, I mean --

MR. CONDE: Our only point --

THE COURT: You're going way beyond my comprehension.

MR. CONDE: Okay.

THE COURT: When you start to talk about some of that, some of this, you're going way behind almost anyone's comprehension.

MR. CONDE: I understand.

THE COURT: Issue before me is, who's the more reliable source, who gives the better spin, who's the more reliable expert.

MR. CONDE: Right.

THE COURT: You have one expert who says he did certain things. I have four experts who said they did it, what is pretty much accepted in the field, in terms of examination, what your doctor did as well. He did these in his own way.

MR. CONDE: Right.

THE COURT: He's standing up here saying, what he did is correct, everything everybody else did is wrong.

MR. CONDE: Yes.

THE COURT: I have to call it. I don't know how much more I need of this. You know. If I gave lawyers in patent cases 60 hours, they would take 60 hours. If I gave them 15 hours, they would take 15 hours. The truth.

Matter is, I've had it about up to here. And unless you all have something much more relevant, let's get on with it. Because I'm not sure I even want to spend tomorrow doing this again.

MR. CONDE: All right.

THE COURT: Because all you're doing is arguing now. You know, you're not creating helpful evidence.

You're both arguing your positions.

I know the positions. I've known it for a day and a half now or more. Okay?

MR. CONDE: Appreciate, Your Honor.

The only purpose of this is to show that this goes to the reliability of the testing. And that's what we're trying to show.

THE COURT: And your doctor says his testing is absolutely reliable, and this doctor is saying no, Mr. Conde, and this doctor is saying he's got the better test.

MR. CONDE: I know -- yes.

THE COURT: You know, I'll call it at some point.

The Federal Circuit will call it.

You're making your records. I've given you all ample time to, you know, make your records. If there's really something probative in making your record, go ahead. That's what I've been doing here. Trying to give you each a chance to make a sufficient record, so if I call it wrong for one of you, you'll have a record to go up on. Okay? You know, I'm finishing this case tomorrow.

MR. CONDE: You know, Your Honor, we're with you. We're set to finish tomorrow.

THE COURT: You know, come hell or high water this case is over tomorrow at 4 o'clock. So I mean, come on, fellows, I mean you know I've given you a lot of time, a lot

of consideration, all of you.

MR. CONDE: You have, Your Honor.

THE COURT: So focus in on what you want to get in the record in the next day and a half and let's do it.

MR. CONDE: Okay.

BY MR. CONDE:

Q I have one more question on -- with regard to the talc, you know, that there's a specific peak for talc that's at 666. Right, Dr. Sommer?

A That is correct.

Q Okay.

And you didn't use, your instruments are uncapable of the detecting the specific peak for talc. Right?

A That's correct. Our instrument cuts off at 720 wave numbers.

Q So if your instrument was able to see 666 wavelength, you could give a specific image as to talc. Right?

A Yes, I could.

Q Could you go to paragraph 46 of Dr. Sommer's report.

Could you blow-it up.

So this is the paragraph in your expert report where you mentioned the band shifts. See right there in like the third line, four, five from the bottom?

A That is correct.

Q And you don't mention anything about an acetone wash

causing the band shift. Right?
A Well, no, it says right there, Dr. Davies ATR-FTIR data on the acetone wash DRC contains evidence of a band shift.
Q I apologize, I misspoke. I should have been more precise.
You don't say there anything about an acetone residue on the outside of the bead, do you?
A No, not in my expert report. But in my deposition I clearly showed that the presence of acetone could explain that band shift.
Q Did you see any acetone peaks in Dr. Davies' ATR-FTIR data on the washed beads?
A Again, when you do these analyses, the peak for HPMCP and acetone is very close to one another. The only way that you can figure out whether that's there is to do the modeling experiment that we did and we provided in the deposition.
Q And you agree -- now, Dr. Davies had a different explanation for the band shift. Right, Dr. Sommer?
A Yes. If I recall correctly, in Dr. Davies' rebuttal to my expert witness report, he noticed an upward band shift.
So if you look at HPMCP by itself, actually, in his data, HPMCP by itself has a band at 1725. In the formulated product, because you're mixing it with a triethyl citrate, that band shifts up approximately three wave numbers.

Now, in Dr. Davies' washing step, when he hits it with acetone, it removes the TEC. So the band shifts back, should shift back to the normal position for HPMCP. But what we saw was a further shift downward of about three wave numbers, and that indicates to me that there was still residual acetone remaining in the beads and the spectra that he recorded.

Q And you understand that Dr. Davies' explanation was based on actual data from his testing?

A I didn't see any data, I just saw his rebuttal statement to my expert witness report.

Q Did you apply the removal of TEC to your computer model for the band shift?

A Yes, at some later point I did, and that was confirmed.

Q You hadn't done that as of the time of your deposition though. Right, Dr. Sommer?

A That is correct.

Q So at your deposition you didn't know what the results would have been for the computer modeling removing TEC. Right?

A No, that is correct.

But I did know the results for the shifting of the HPMCP band as a result of mixing with acetone.

Q And you agree that the band shift could be caused by the removal of TEC. Right?

A Can you tell me which band shift you're talking about?
Q I'm sorry. You agree -- well, in the band shift that you were referring to could have been caused by the removal of TEC. Right?
A Yes.
MR. CONDE: I have nothing further, Your Honor.
THE COURT: All right.
Thank you, Mr. Conde.
Any redirect?
MR. SCHEFFEL: No, Your Honor.
THE COURT: All right.
Doctor, you can step down.
THE WITNESS: Thank you.
( Witness excused ).
THE COURT: We'll take a recess until five after, please.
MR. WEISBLATT: Your Honor, I know Mr. Conde was able to tell you, I believe it's almost a certainty that we will be done with this case in the time you just mentioned. We do have to create a record, but we will be done, in fact I hope to be done earlier. But we will be done.
THE COURT: I know. I'm just saying.
MR. WEISBLATT: But I --
THE COURT: I don't want to shortcut anybody. But you know, we have an estimate, we're on target anyhow.

MR. WEISBLATT: Yes, Your Honor.

THE COURT: But I just want to be sure that you don't waste time -- not waste time, but you know, I mean look, I understand the respective positions. You know, as best I can.

Some of the technicalities you get into are, you know, only they, Doctor and Dr. Davies would fully understand, and you.

But I have an understanding as to, you know, what I have to decide, and so -- and I'm, you know, I think you're almost done with the affirmative case anyhow. Correct? You have another witness?

MR. WEISBLATT: Yes, Your Honor.

Again, we have Dr. Kibbe.

THE COURT: Okay.

MR. WEISBLATT: Who will perform essentially the same function as I believe it was Dr. Bucton in the Mylan case.

THE COURT: Okay.

MR. WEISBLATT: And again, Your Honor, you also mentioned yesterday in passing that, you know, if we had to go longer and take heroic efforts to finish, in looking at what's left, we don't need to do that. We have Dr. Kibbe and then we have an adverse witness we're going to call, and then we have the invalidity case, which is Dr. Kibbe and Dr.

McGinty. I do not believe --

THE COURT: Are those the two witnesses as to the invalidity case?

MR. CONDE: Yes, Your Honor. There's only two. And any -- the adverse witness, which I think should only take probably about a half hour at most. I don't believe we have any issue with heroic method or staying.

THE COURT: Okay. I just want to impress upon you, you know, you understand we'll be done.

All right. We'll see you at five after 11.

MR. WEISBLATT: Thank you, Your Honor.

THE COURT: Thanks.

( After a brief recess court resumed ).

THE CLERK: Please remain seated.

THE COURT: Okay. Ready to proceed?

MR. PACELLA: Yes, Your Honor.

THE COURT: All right.

Go ahead, counsel. Introduce our next witness.

MR. PACELLA: And I forgot to introduce myself the other day, I'm Mark Pacella representing Impax. And the next witness is Dr. Arthur Kibbe.

THE CLERK: Left-hand on the Bible, raise your right hand.

D R. A R T H U R H. K I B B E, sworn.

THE COURT: Okay.

THE CLERK: Please state your full name and spell it for the record.

THE WITNESS: Arthur Hamilton Kibbe. A-r-t-h-u-r, H-a-m-i-l-t-o-n, K-i-b-b-e.

THE CLERK: Sir, you may be seated.

MR. PACELLA: Your Honor, may I approach.

THE COURT: Sure.

MR. PACELLA: These ones are a little thick. I apologize.

May I proceed, Your Honor?

THE COURT: Sure. Go ahead.

DIRECT EXAMINATION

BY MR. PACELLA:

Q Good morning, Dr. Kibbe.

A Good morning.

Q Dr. Kibbe, you understand that the plaintiffs contend that Impax's proposed doxycycline hyclate tablets infringe certain claims of the 161 patent?

A I do.

Q You are here today to offer your opinions regarding those allegations?

A I am.

Q What is your opinion?

A I do not think that the Impax product infringes the claims of the 161 patent.

Q Where are you presently employed?
A I'm employed at the Wilkes University's Nesbitt School of Pharmacy.
Q And how long have you been there?
A I began my employment there in 1994.
Q What is your position?
A I'm a professor and chairman of the pharmaceutical sciences department.
Q Do you teach?
A I teach, provide service on a committee work and do some research and oversight, yes.
Q What sort of classes do you teach?
A I teach basic dosage form, design and dosage form evaluation for pharmacy students who are becoming pharmicists in the community.

I also teach a class in bio-pharmaceutics and pharmacokinetics. I teach formulation and manufacturing to our undergraduates who are enrolled in the Bachelor of Science and pharmaceutical sciences, which leads them to be technicians in the formulation or formulating area.

Q When you say "formulating," what do you mean?
A Formulating is the discipline within the pharmaceutical industry that is involved with taking an active pharmaceutical ingredient and converting it to a use dosage form to be used by the patient or caregiver.

Q Will you please briefly describe your educational background.

A I graduated from Columbia University in 1966 with a Bachelor's Degree in pharmacy.

I then matriculated at the University of Florida and obtained a Masters Degree in pharmaceutics in 1968.

I was then asked to serve two years of sabbatical with the military in Southeast Asia, and I returned to graduate school and finished my PhD in pharmaceutics at the University of Florida in 1973.

Q And what is "pharmaceutics"?

A Pharmaceutics is the science that's involved with the dosage form and not the active ingredient. So that the different disciplines within pharmacy include those that are the care, about how the active ingredient works in the body, and those that care about how we can develop a delivery system for that active ingredient that gives us the best outcome in the patient.

Q And have focused on any particular aspects of pharmaceutics during your career since you obtained your PhD back in 1973?

A Yes.

I was very interested in delayed release or extended release dosage forms when I was training as a PhD student. One of my professors was a gentleman by the name

of Reed Blythe, who invented the **Spansol which was the first patented delayed release bead system. So most of my career I've kind of looked at oral solid dosage forms, I've looked at delayed release methodology for oral dosage forms, evaluation of dissolution and the relationship between dissolution numbers and the pharmacokinetics of the drug.

Q Okay.

And I don't know if you mentioned the word excipients, but what is an "excipient"?

A I'm sorry, I should have.

Excipients are the materials that are used to make a dosage forms that have no pharmacological effect.

Q So everything other than the active ingredient?

A Yes. They're all the inactive ingredients in the dosage form.

Q What's your experience dealing with excipients?

A I have had the opportunity to work closely with the steering committee and actually be the editor of the Third Edition of the Handbook of Pharmaceutical Excipients, which lays out into monograph form the characteristic of excipients, what they're used for, what you can expect to expect with the use of them, and what they are, their characteristics in terms of their physical and chemical nature.

Q Okay.

Prior to joining Wilkes University, did you teach at other universities?

A I did a stint at the University of Mississippi for approximately ten years.

I was thereafter at the National Institutes of Health as Chief of Pharmaceutical Development for a couple years. We provided pharmaceutical services in terms of formulation development for the intramural work done at the institute in Betheseda, Maryland.

Then I worked in industry. I was Chief of the Scientific and Professional Affairs for the American Pharmaceutical Association, and I continued my involvement with the Food and Drug Administration as a member of the Pharmaceutical Sciences Advisory Committee which I chaired from 2002 to 2004.

Q Okay.

What did you teach at the University of Mississippi for ten years?

A I taught basically the same things I teach now, except that at the University of Mississippi we had both undergraduate and graduate degree programs, and so I trained formulators who went out in the industry and worked as senior formulators in various companies in the United States.

Q Have you been a reviewer or editor for scientific

publications in the field of pharmaceutics?
A Yes. I've had an opportunity to be a reviewer in a number of journals. Most recently, Pharmaceutical Development, and of course the Journal of Pharmaceutical Sciences, which was the, I guess you'd call the flagship of our industry.
Q In the course of your work, do you keep up to date with the scientific literature in the field of pharmaceutics?
A Yes. In order to continue to be able to consult, to do research and to teach on the areas you have to keep up with the literature.
Q And you mentioned the Handbook of Pharmaceutical Excipients. Again, what role did you play with respect to that?
A I've been on the steering committee for the handbook since the Second Edition and continue to this day doing that.

I wrote monographs for the handbook which are in the various editions, and I was Editor-in-Chief of the Third Edition, wherein we did a lot of testing ourselves to add information to the monograph from direct testing by volunteers within the steering committee.
Q And is the Handbook of Pharmaceutical Excipients a recognized reference for those who work in the field of pharmaceutics?

A Yes. It's internationally known as a reliable reference with respect to the characteristics of excipients.
Q Have you contributed to or co-authored any other portions or books -- portions of books such as chapters?
A I wrote a text for the Encyclopedia of Pharmaceutical Technology on the generic drug process, and then I've written a chapter on the theory of dissolution for a book on dissolution theory, methodology and testing.
Q And do you have a curriculum vitae that provides additional detail about your educational training and professional background?
A Yes, I do.
Q Could you please turn to ITX 657?
A Yes.
Q And do you recognize that?
A Yes, it is my curriculum vitae.
Q Does that document accurately reflect your professional background?
A Yes, it does.
MR. PACELLA: Your Honor, Impax offers Dr. Kibbe as an expert in the design, manufacture and evaluation of pharmaceutical dosage form, including modified release dosage forms.
MR. CONDE: No objection.
THE COURT: All right.

Without objection he's so qualified in that area.

Thank you.

BY MR. PACELLA:

Q Okay.

Dr. Kibbe, let's talk about your opinion that Impax's product does not infringe the claims of the 161 patent.

Now, I understand you were unable to attend the trial last week because you had some teaching commitments?

A I'm a full time faculty member and actually should be teaching today, and this week I managed to get some coverage from my colleagues. But I couldn't get as much coverage to be here for the whole time.

Q Okay.

But did you read the transcript of Dr. Davies concerning Impax's doxycycline hyclate delayed release tablets before today?

A I did read the transcript.

Q Did you prepare some sides that would help you in explaining what you'd like to discuss with the Court today?

A Yes, I did.

Q Do you have a slide that highlights the key claim limitations that you're going to be discussing today?

A Yes, I believe it's slide one.

MR. PACELLA: Could we have slide one.

BY MR. PACELLA:

Q Doctor, could you explain slide one?

A What I've selected was the two independent claims of the 161 patent, and I've highlighted I think the two key elements in determining whether or not Impax's product infringes.

First that the patent calls for a modified release preparation. And of course, preparation is broad, and it includes various kinds of pharmaceutical dosage forms. The 20 -- Claim 20 limits it to a tablet. And that tablet being a modified release preparation. Okay. So Claim 1 could have also covered capsules or other methodologies.

The second thing I highlighted is I think the crux of the discussion, and I've been here listening to all the experts talking about whether or not there is a stabilising coat. And in addition, the issue, the crux I think of the issue wherein a stabilising coat is provided between each core element and its modified release coat.

Q Is it your understanding that these are the only two independent claims that are being asserted?

A Yes, it is.

Q So, and your understanding that each of the limitations of these two claims is required in each of the other claims that have been asserted against Impax?

A That's my understanding.

Q Now, did you review the 161 patent in connection with reaching your conclusions in this case?
A I did.
Q And did you consider the Court's claim construction of the, specifically these two terms in reaching your conclusions?
A I did.
We have a slide with the Court's claim construction on it.
Q Sure.
MR. PACELLA: Can we go to slide two, please.
BY MR. PACELLA:
Q Dr. Kibbe, can you explain what your summary of your opinions is based upon the claim construction?
A Right.
The core construction is that a layer of material in between each core element of a modified release coating, that's a very good description of what I think was intended by the patent, and that is not present in the Impax product.
Second, the Court, it says it keeps the migration of co-materials to -- core materials to a minimum, etcetera. And of course that comes directly from a quote within the patent itself.
But there have been no testing done on any of the product, Impax product that shows that this alleged coat

which Dr. Davies claims is really there actually does keep migration to a minimum or contribute to the dissolution stability. Okay?

Next, we talk about the modified release preparation. And the modified release preparation is the completed tablet. All right?

And there was no testing that showed that the total modified release preparation provides its claim dissolution stability in and of itself.

Q Okay.

We'll get -- drill down into this as we go.

Let's first talk about the term "modified release preparation."

MR. PACELLA: Can we see slide three.

BY MR. PACELLA:

Q Doctor, can you explain what's depicted on slide three?

A Okay. We had highlighted again from Claim 1 the same in Claim 1, a preparation provides a release profile for an active ingredient that's different from an immediate release preparation. Which means that the dosage form itself is the preparation, the tablet or capsule, or whatever you actually give to a -- to a patient. And that preparation is to have the release profile, and in fact the stability of the release profile according to this patent.

Q So you have some slides there to help explain why it is

that your opinion is the modified release preparation according to the claim construction is in fact the tablet or the final dosage form?

A Yes, I do. We have another.

MR. PACELLA: Slide four, please.

A I've stylized this so we could go through it quickly.

The dissolution medium is, the dissolution apparatus is usually prescribed by the United States Pharmacopea, USP, and it's approved or accepted by the FDA. And we do standard testing on every batch of solid dosage forms that are intended for oral administration.

And what we do is we take the actual dosage, and we put it in a medium at a certain temperature, with a certain number of RPMs, on a paddle, stirring it, and we collect samples of that fluid over time, and measure the percent of the drug that has been released from the dosage form.

And what I tried to show is the difference between an immediate release, which gives you a very rapid uptake and finishes delivering all the drug in a very short period of time, and a modified release, which is what we're talking about here, which will give you a very slow release of drug over time. These are stylized and not to be confused with any real data about the Doryx or anybody's product.

Q Okay.

And so what's being tested when you are talking

about a release profile as opposed to stability of the release profile is the tablet itself?

A Yes.

Q Does the container tablet -- I'm sorry, does the container that the tablet or the capsule or what you have tested is in -- let me start over. I'm sorry.

Does the container that the tablet is packaged in have any influence on the dissolution profile that is produced by the modified release preparation?

A No. It's -- obviously you don't take the whole bottle and throw it in the dissolution preparation. What you do is take the modified release preparation for dissolution and you take it out of the container.

Q Do things such as the dessicant or the cotton, things like that that are placed in the bottle, does that have any influence on providing a release profile?

A No.

Q Sod does the term "modified release preparation," include the bottle sealed, cotton, dessicant, things like that outside the tablet?

A No, it's just the tablet itself.

Q Okay.

Let's move on to the stabilising coat.

You heard a lot of testimony when you were here, when the experts for Impax testified about their view as to

the stabilising coat in -- on Impax's product?
A I was here for of Dr. Sodhi's and Dr. Sommer's testimony about their testing of the possibility of a presence of that, yes.
Q And you were -- and again, I believe you said you read Dr. Davies' testimony on that issue?
A I did.
Q Does the patent --
MR. PACELLA: I just wanted to walk through, Your Honor, you might have heard something about this from Dr. Buckton. I just wanted to try to clarify this.
BY MR. PACELLA:
Q Dr. Kibbe, have you prepared some slides that would describe, according to the patent at least, how the modified or the stabilising coat is supposed to work on the shelf as opposed to in the body?
A Yes, I have.
MR. PACELLA: Could we have slide five.
A I hope -- it's a quick animation, and we won't keep the Judge long.
When the product is made we have a bead with an active ingredient in it, and that's orange. And then the stabilising coat, purple, and the enteric or delayed release coat in green.
And the patent claims that the function of it is to

minimize movement from the core to the delayed release coat or vice versa. So that's what the patent is talking about. And that's when the product is on the shelf in its container.

All right. When we give the product to the individual, we have the same product, it's in a form in this case of a tablet. When it enters the stomach it is now in a fluid medium. And once there, the fluid begins to enter through the membrane. And these are -- the purpose is really a semi-permeable membrane, so it allows water in.

The design of the enteric coat is not a subject of this patent. But it's designed to allow drug out at the rate that you want it to be let out.

The drug in the center dissolves, migrates through the pemeable membrane, through the pores or what have you on the outside, and come out.

Now, when it moves from the stomach to the intestinal tract, those two layers dissolve away. The enteric coat that's used, in this case HPMCP dissolves rapidly in a Ph above five. In which case it dissolves away.

The barrier coat, according to the patent, has to be made of material that will also readily dissolve away and not interfere or change the release of the drug from the core. And it, the patent suggests HPMCP, and so that also

sloughs away or dissolves away rapidly, and then the rest of the ingredients in the core all go into the solution. And so that way we guarantee that a limited amount of material is released in the stomach and the rest of it is all released as quickly as possible once it gets to the intestinal tract.

Q And what's the difference between why -- what is it that explains why once you ingest the pill and it's in the stomach the layers will dissolve versus what you see on the left-hand side where the layer is supposedly not allowing migration to take place?

A Well, you understand that this is a dry bead in a tablet sitting there. When you put the tablet either in a dissolution medium or in the stomach it is now surrounded by fluid. And that fluid, with the water, penetrates into the tablet and begins the process of dissolving away and swelling and material comes out.

The reason we have a reduced amount of material come out in the stomach is because the integrity of the delayed release coat, because of the phthalate derivative of cellulose will not fall apart. And so it only allows some drug to migrate through this coat. When it hits the intestinal tract, that whole thing falls apart and then everything comes out.

THE COURT: Does it fall apart at the same rate,

the delayed release coat and the purple stabilising coat?

THE WITNESS: The critical thing to fall apart is the delayed release coat, when water starts to get in there the barrier coat, which is made of something that's water soluable, begins to become hydrated and swell. And if there was no delayed release coat on it, it would go off right away. But it's being held there because the delayed release coat surrounds it.

Now, as soon as the delayed release coat falls off, the other one's ready to come off and it just drops right off.

THE COURT: Then how does the application of a stabilising coat have any bearing on what the invention is supposed to do, and that is, to minimize dissolution in the stomach and I guess encourage further dissolution in the lower stomach and upper intestine?

THE WITNESS: Okay.

THE COURT: So it's the delayed release coating that has the primary, or keeps the tablet secure until it hits the dissolution material, and you're saying the stabilising coat would come off right away?

THE WITNESS: Okay. Your Honor, the patent doesn't set the criteria for dissolution. The patent sets a coat which helps to stabilize that criteria. And so the dissolution pattern is all controlled by the delayed release

coat, the green coat. The benefit of the barrier coat is that it prevents things from migrating into that coat while on the shelf. And changing its ability to behave the way it should.

So it's kind of like a safety net for the delayed release coat. When water gets in, in a situation where you're going to put it in either a dissolution medium in the laboratory or a patient is going to swallow it, now we're talking about this tablet sitting in a cup of water.

THE COURT: I understand that.

THE WITNESS: And so once that happens, water starts to migrate in. And then the whole thing starts to fall apart. And the coat on the outside will not give away until it reaches the correct acid concentration in the intestine.

THE COURT: And if I'm going beyond your expertise just please so indicate. But if you just made the delayed release coat thicker, would that accomplish the same thing as having a stabilising coat?

THE WITNESS: The problem with changing the delayed release coat is it will change the dissolution pattern. The thicker you make that, the slower that pattern will be. So what has happened is in the prior art, Doryx's capsule, they established an initial manufactured dissolution pattern which is best for the patient in terms of side effects and

bio-availability. That's not in this patent at all.

All we're doing here is we're saying once we've developed that coat, and we notice that it begins to degrade with time, how can we keep it working exactly as we intended it to. If we didn't care about the dissolution pattern staying the same, as we had already decided upon, then sure, we could make the coat thicker.

THE COURT: All right.

THE WITNESS: But it wouldn't give us the same dissolution pattern that we already had. And this is a patent that improves an already existing product that has certain characteristics. And if I don't want to mess with those characteristics, then the thing to do is to put a coat in there that stabilizes the already exiting delayed release coat.

THE COURT: All right. Thank you.

A Okay. I'm sorry.

Q And I don't want to belabor this slide, but I just had a couple questions on the left-hand side.

A Sure.

Q Now you're describing there what the patent, and I believe you cited, quoted the language underneath --

A That's right.

Q -- how patentees intended the stabilising coat to work. Correct?

A That's correct.
Q And are you saying that in any particular formulation that the stabilising coat is required to prevent migration or that migration would otherwise occur in the absence of a stabilising coat?
A No. The patent -- the patent and the test data in the patent shows that when they apply this intermediate coat they improve the stability of the dissolution pattern that is taking tablets and storing it for a period of time and then testing dissolution. Other products don't have a stabilising coat because they don't need it, because the interaction between the delayed release coat and the core is such that it doesn't materially affect the quality of the delayed release coat. And so you don't need it.

Or there is another factor that they've taken care of or included in their product that means that that isn't required. Very few products have to have this coat. But this coat has been around since time immemorial almost. When I was an undergraduate they were already talking about using seal coats and coats and these kind of coats to protect coated dosage forms from back in the 30's and 20's. So it's a common enough tool, but it isn't -- doesn't have to be used universally in every single tablet or oral dosage.

THE COURT: Does the composition of the sealed coat

make a difference -- obviously, there have to be certain chemicals that make the seal coat. Correct?

THE WITNESS: Absolutely, Your Honor. You want a polymeric material that is readily dissolved in water and absobs water and swells, because you want it out of the way when you take it. All right?

You don't want something that's going to make it even more difficult for the drug to come out, you know.

Q And --

A If we had time to digress, I'd talk about it a little.

Q Let me ask a little follow up on that, because you cited the language in the body underneath -- underneath the patent language that says, while still allowing for a release of core materials in aqueous environment. And so according to the patent and according to your understanding of the type of stabilising coat that they describe, will that, should that interfere with the release of the drug once the pill is in the body?

A No. It's not supposed to. It's designed not to.

Q And just to be clear, do you have an opinion as to what, whether the mere fact, Impax's product, is there any evidence that without a stabilising coat, have you seen any evidence that without a stabilising coat Impax's products would have this migration issue that is depicted on the shelf as described by the intended use of the patentees?

A That's the theory that the patentees put forward. And there has been no testing that I know of that was performed to look for migration in the Impax product.

Q Okay.

MR. PACELLA: And we'll touch on that a little bit more later, Your Honor.

BY MR. PACELLA:

Q Dr. Kibbe, have you reviewed Impax's abbreviated new drug application?

A I have.

Q And have you seen abbreviated new drug applications in the past?

A Yes, I have.

Q Have you read in Impax's -- can we call it ANDA?

A Yes, that's the revision form.

Q In that document, have you read the descriptions of the ingredients that are used and how the Impax product is made?

A Yes, I have.

MR. PACELLA: Your Honor, we're going to get into a significant area where we're going to describe Impax's product. Can we seal the record?

THE COURT: Yes. From this point on the record will be sealed and please indicate when we should unseal.

MR. PACELLA: I will, Your Honor.

( Record sealed ).

BY MR. PACELLA:

Q Doctor --

MR. PACELLA: Can we have slide six.

BY MR. PACELLA:

Q Dr. Kibbe, can you explain -- this was shown when we had the opening statement, but you were not here. But can you explain, based on your reviews of Impax's NANDA what this slide shows about the composition of Impax's product?

A This list comes directly out of the Impax NANDA and I color-coded just to divide it up into it's component parts so it's easy to follow.

The active core, which is in orange, includes the active ingredient and then a series of excipients: Sodium chloride, microcrystalline cellulose, lactose and HPMC and lauryl sulfate.

Q Can I stop you, you said HPCM. And the slide says hypromellose. Is that the same thing?

A I apologize. Hypromellose is the generic of HPMCP, hydroxypropyl methycellulose is what it is chemically, and HPMCP is the abbreviation of the chemical. And when you work in the industry you kind of throw those names around like you know what you're doing. Pharmacoat 606 is a particular brand of it. It's not -- it's just, you know, people make it. I don't even remember the name of the manufacturer. But Dow makes it, several other companies.

Q Okay.

And I didn't mean to interrupt your flow, if you could just please continue with the composition of the Impax product.

A Okay.

Then the active core seed, once it's manufactured, is coated with a delayed release coat. And that includes hypromellose phthalate, or HPMCP, and specifically HP 50. Some additional HPMC, Pharmacoat 606, triethyl citrate, which is a well known plasticizer, and talc, which is in as a anti-sticking agent.

Once that coating is completed, those beads are blended with tabletting excipients. And to make the final blend. And so the final blend is in white, and it includes the beads, the lactose, corn starch, crospovidone and magnesium sterate and then it's made into a tablet.

Q And the tablet is the modified release preparation?

A Yes, it is. That's the final preparation.

Q Now, is there any difference in the ingredients that are used to make the Impax different strengths, 75, 100, 150 milligram tablets?

A No.

What Impax does is they make an active core seed and they coat it with a delayed release seed, and then they use that seed in each one of their strengths by just upping

the number of seeds, or the weight of seed per tablet, and upping the tote weight of the tablet. So that all the ingredients are proportional and the tablet weight is proportional in -- on the amount of active ingredient. So the 150 milligram tablet weighs twice what the 75 milligram tablet weighs.

Q Okay.

You mentioned that talc was used in Impax's product as a ingredient or anti-stick agent?

A Yes, that's true.

Q Why do you do that?

A During the process of coating, and we'll see a spray coater and I'll try to explain what goes on.

But the beads are being coated with a film in a solvent. And they become slightly sticky. And in order to prevent those beads from sticking together during the manufacturing process, we put talc on them. And so you incorporate talc in the coating liquid or the spray coating solution so that the beads won't stick together, so they'll be discrete, independent beads when they finish the coating.

Q And do you want this talc that's keeping the pellet from sticking together to be all around the pellet, is it the same general amount all through the coating process?

A It has to be uniformly distributed to have its effect during the entire coating process.

Q Is that an unusual use of talc?
A No.
Q Based on your experience and your review of Impax ANDA, is there anything out of the ordinary about any of the ingredients that Impax used to make this type of product?
A No, these are common excipients well-known to be useful in these situations.
Q In looking at the delayed release seed that you had as your middle picture, so to speak, illustration, based on the composition and your review of the manufacturing process, what does that -- that seed, the delayed release seed consist of?
A The delayed release has the active core and a single delayed release coating.
Q Will you turn to ITX 632 in your binder. And do you recognize ITX 632?
A Yes.
Q And what is ITX 632?
A This is an excerpt from the Handbook of Pharmaceutical Excipients, Third Edition.
Q I see your name on the top cover there. Is that the edition that you edited?
A That's the edition that I edited, yes.
Q And so what -- can you just generally describe what's contained within ITX 632 without going into every single

detail?
A Okay.
We have a series of monographs here. Each monograph describes the characteristics of the excipients that are used in the Impax product. So all of the Impax product excipients, they're a monograph in here that matches up with them.
Q Okay.
And did you find anything that Impax does with its ingredients that's inconsistent with the uses that are explained in the various monographs of Exhibit 632?
A No.
Q Now, based on your experience and your review of Impax's NANDA, would you expect any reaction to occur within any of the ingredients you went through when you were describing the composition?
A No, I wouldn't.
Q Why not?
A Well, these are common excipients that are, have been blended in many different preparations in the past. I myself have used those myself. And even Dr. Davies agrees that he would not have expected any reaction to occur.
Q Have you seen anything in the scientific literature that would suggest a reaction could occur between the ingredients of the delayed release layer to the active cores to form a

separate layer between the cores and the delayed release coat in Impax's product?

A No.

Q Have you seen any evidence in this case of such a reaction that could form?

A No.

Q Have you heard any explanations from Dr. Davies as what reaction could occur in Impax's product to form such a layer?

A He doesn't talk about how that reaction occurs, no.

Q Okay.

I'd like to briefly now walk you through the manufacturing process and try to be brief. But have you prepared some slides on how Impax makes its product?

A I have.

MR. PACELLA: Let me go to slide seven.

BY MR. PACELLA:

Q And, Doctor, could you -- could you please walk the Court through how Impax's product is made?

A Okay.

Okay. So what we start with is our basic dry ingredients that are blended in a dry blender. And then we transfer to a mixer that allows us to add the water, sodium chloride solution to moisten the powder. The powder is now moistened to a state a little bit dryer than what you have

-- you would have for pasta. When you're making it at home, I don't know whether you ever make egg noodles or pasta. And then we push it through an extruder. Which crudely looks like a meat grinder. It has a force, it pushes it through some tiny holes. This almost spaghetti like strand comes out, there's a blade that spins it, cuts it into pieces. Those pieces are then rounded as best we can in a sphereonizing and those result in active core seeds that are died.

Q Okay.

Go to the next step, please, slide eight.

A Okay.

Now we're going to coat these seeds with our delayed release coat.

So what Impax does is they first make a mixture of 30 parts water and seven parts acetone. And they put it in a container and they begin mixing it and create a vortex, so they're mixing it very aggressively.

And then they add these three ingredients as dry powders. Because those ingredients are indeed soluable in the 30 parts water, 70 parts acetone mixture that Impax uses.

And they mix them for a minimum of ten minutes to get them to all dissolve. Once they're all dissolved, then they take the talc, which is not soluable, and they add it

to that mixture with a vigorous stirring and they get the talc to distribute.

Talc is very fine particle in insoluable material. And then it's mixed to a uniform distribution.

That material is then pumped into the sprayer dryer -- I mean the spray coater. The beads have already been installed in there. And as the material liquid is pumped in from the bottom and sprayed in, it coats the beads over time and eventually you get the delayed release coated seeds.

Q Okay.

Before we move off of this one to the next step, why -- what is the purpose of using 70 percent acetone, 30 percent water as the solvent?

A Okay.

What you want to try to do is get all the soluable ingredients to dissolve. And at the same time not have your coating solution adversely affect the surface of the core seed.

And so what you often do, because water has a tendency to really migrate into seeds and affect it, you often use a minimum amount of water that will allow you to get all those things dissolved so you can get a good coat.

Also, acetone evaporates more quickly than water. And if you want to minimize any distribution or any changes

in the nature of the core seed -- of the delayed release coated seed, you want the solvent to come off as quickly as possible.

Q Okay.

What is the -- I think you mentioned that the purpose of a mechanical stirring was to create a vortex that distributed the ingredients before they were sprayed?

A That's correct.

Q Would changes in the rate of stirring that mixture in, they were adjusted during the coating process, do you have an opinion as to whether that would affect how the ingredients are distributed within the layer as it's being applied on?

A That's very good.

Once we have the coating solution uniformly distributed and ready to go we start pumping it in. As we pump it in, the level of the coating solution in our container goes down.

If we get to a point where we're starting, the vortex starts to draw air into our coating solution, it causes foaming. And that creates a problem for us in terms of the manufacturability and in the coating. And so we might slow the stirring near the end of the coating process to allow us to have the -- continue to have the uniform coat.

Q Based on your knowledge and experience of Impax's NANDA, how would you characterize the way in which the four ingredients used to make this delayed release seed are distributed within that delayed release layer?

A The three ingredients are successfully dissolved in the liquid to form a homogenous uniform layer. Talc would be distributed uniformly throughout that layer.

Q And when you say "uniformly," do you mean perfectly uniform?

A Well, talc has a tendency to aggregate. So individual particles could be seen or larger aggregates within the coating layer. But they would be throughout the thickness of the coated layer.

Q Okay.

Could you move on to the next step of Impax's process, which I believe is slide nine.

A And this is fairly straightforward.

What we do is we take these beads that have been successfully coated with the delayed release coat, we blend them with powders. All right?

And then we send it to -- through the tablet machine and compress it into a tablet.

Q Okay.

And you have up there 75 milligram, 100 milligram and 150 milligrams tablets. Is there any difference,

significant difference in the manufacturing process for those three different tablets from what you just described?

A The only difference is the size of the actual tablet itself. The total weight of each individual tablet goes up.

Q Okay.

Based on your knowledge, experience and review of Impax's ANDA, what is your opinion as to whether or not the Impax product, the tablet, or I should say the delayed release seed has a separate stabilising layer between the core and the delayed release coating that is made up of what Dr. Davies has said is a HPMCP derived material and is talc enriched?

A I think that's impossible.

Q Have you ever been to Impax's manufacturing plant to actually watch them make the product?

A No, I haven't.

Q Does that affect your opinion in any way?

A No.

If you look at the executed batch records you can see step-by-step how they go about it. The steps they use are exactly the steps I use in my own laboratory.

I have a pilot plant or a laboratory sized equipment that matches all of this equipment except for the extruder, which if someone wants to give me one that would be good, so I can go about and make these products and teach

people how to make them. And this process is exactly the ones that we would use.

Q So based on your knowledge, experience and review of Impax's ANDA, do you believe that information is sufficient for you to conclude what you just concluded in terms of the distribution of the components in the delayed release coating?

A Yes.

Q I'm sorry, I should say, I misspoke and I said delayed release coat, I did misspeak, but let me just ask the question. I apologize.

From your knowledge, experience and review of Impax's ANDA, does that provide you sufficient information to reach the conclusion that you did concerning the distribution of the four ingredients in Impax's delayed release coating?

A Yes, it does.

Q Now, could you just -- we want to be brief, but do you have experience with the types of processing steps that you described that are used to make Impax's product?

A I think I said already that I have that equipment in my own laboratory, I use it on a regular basis, I teach people how to use it. So yes.

Q Do you have an understanding of how to use the types of equipment that Impax uses on a larger scale than what's in

your lab?
A Yes. I've visited other companies and worked with them doing scale-ups, so the basic principles of the equipment are the same and there are of course subtle differences in scale up.
Q Have you seen anything, anything in Impax's ANDA which would suggest a second layer would somehow form in Impax's delayed release coat seeds?
A No.
Q Have you seen anything in the scientific literature that would suggest that the processing steps would somehow lead to a stabilising coat in the active core and the delayed release coat of the Impax delayed release seeds?
A No.
Q Now, we've talked about the process all the way through the making of the tablet.

What does Impax do next after it makes the tablets?
A It packages them in a sealed container with a dessicant.
Q Okay.

What is a "dessicant"?
A A dessicant is material that draws moisture out of the environment and therefore it's presence in a sealed container would dry out the air in that container.
Q Okay.

Could you look at ITX 661 in your binder.

Do you recognize ITX 661?
A Yes, I do.
Q What -- what is it?
A It's the quality overall summary that was part of an ANDA 091132.
Q Is that the 150 milligram doxycycline hyclate delayed release tablets?
A Yes, I believe.
Q And does the information contained in this quantity overall summary concerning the manufacturing process and the composition of Impax's product consistent with what you described to the Court earlier?
A Yes, it is.
Q Could we go to page 11 of exhibit 661. And I'm referring to dash 0011 in the lower right-hand corner.
A Yeah, I'm here.
Q Okay.
And is that where you find -- can you explain where you find information that describes the composition of Impax's product?
A This is the beginning of it, and it says that note that the subject of this ANDA is for 150 milligrams strength only. Okay.
Q And where -- yes, can you just --
A I'm sorry.

Q -- provide the Court with the span of pages that describes?
A Okay. So that's where that says, so that's why we know it's a 150. And then the next page lays out the ingredients for all three batches. So we can go to that. And you can see the ingredients. Whoops.
Q I just want you to describe, I'd rather just not show it on the screen, has a lot of detail we don't need to get into.
A All right. Okay.
Q I was just trying to make it simple. What is shown on Exhibit 661, scanning from pages 11 through 13?
A Yeah, the composition and manufacturing requirements for the product.
Q Okay.

And I -- let's go to page 23.

And is this where the manufacturing process that you described on the screen is described in some more detail?
A Yes, it is.
Q And does that go through page 25?
A It goes through page 24, and then on page 25 is the flow chart for it.
Q Okay.

And that's where you drew the information for your

description of the manufacturing process?
A Yes. This and the executed batch records.
Q Okay.
Let's go to the executed batch record.
Have you -- you know -- now, what is a executed batch record?
A When a product is actually made there is a batch record. And the batch record starts out with a -- we call a ticket, which says to the people who are going to make it, these are the steps you have to follow to make this product. And then it leaves spaces for them to fill in the information that they needed to have to assure that they actually did what the batch record said. And then they initial it. So an executed one would be one that had been carried out by a team of formulators.
Q Okay.
Can we go to ITX 214.
What is ITX 214?
A Okay.
Okay. So this is the executed batch record for lot RO 8071. And it's divided up into its individual segments. And so this cover page says blending, but there are other segments in this document that cover each of the different activities.
Q So does this document, ITX 214, include all of what was

done to manufacture an actual batch of Impax product from start to finish?

A Yes.

Q And for this particular one, it's a 150 milligram tablet?

A That's correct.

Q Now, you mentioned lot RO 8071. Have you seen that lot before in this case?

A Yes. This is the lot that was given to Dr. Davies for his testing.

Q And have you reviewed the testing that Dr. Davies did on lot RO 871?

A Yes, I have.

Q RO 8071.

A Yes, I have.

Q Could we go to page 37 in the lower right-hand corner. And I believe there were a couple points you wanted to highlight about this. Which part of the product manufacturing process does this document address?

A So these are the steps involved in the coating. And step one is the blending of the two liquids. We want to look at one, two and three, if you don't mind. Thank you.

So step one is where they blend the two liquids and get it mixing. All right?

And then step two, they add the three soluable

ingredients, which are the HPMCP and the TEC. And they stir for at least ten minutes. And you'll see on the right that the initials of the person who did it and the date when they did it, and what you don't see is the person who verified signs next to that. But we just didn't pull down quite enough.

And then you disperse the talc into the solution, which is step two, and mix for at least ten minutes, and continue mixing throughout the coating process, and then the recorded information and again the initials of the person who did the work.

Q In this step two refers to that vortex that you were talking about?

A Yes, it does.

Q Is this information that's contained in these three processing steps relate to how the materials are distributed within the delayed release coating?

A By doing it in this way we ensure that we first develop a homogenous solution, and then we get a uniform dispersion of the very small particles of talc.

Q Now, briefly just turn to PTX 264. And that's probably very -- in the back, towards the back of your binder.

A I'll be there in a second.

Q You with me?

A I'm there.

Q Okay.

What is PTX 264?

A This is a portion of an executed batch record and it's the stability batch for that RO 7134.

Q And that's a Impax 75 milligram doxycycline hyclate delayed release tablet?

A That's correct.

Q And this is relating just to the coating step, the delayed release coating step?

A Yes, on 007 we have exactly the same information we saw before.

MR. PACELLA: Now, I think we can unseal the record at this point, Your Honor.

THE COURT: All right. The record will be unsealed.

( Record unsealed ).

BY MR. PACELLA:

Q Okay.

Doctor, let's switch gears and talk about some of the testing that's been done in this case.

Do you rely on any testing that you yourself performed in this case to reach your conclusions?

A No.

Q Have you considered testing done by others in this case in order to reach your conclusions?

A Yes.

Q And did you consider the testing by both Dr. Davies as well as Impax's experts Dr. Sommer and Dr. Sodhi?

A Yes, I did.

Q And in the course of your work at the university and in the past, have you had occasion to consider testing done by others and evaluate that to reach conclusions similar to the types of conclusions you're drawing here?

A Yes.

As a formulator you always depend on analytical services to give you information that will help you inform your opinion about the quality of the formulation.

Q Now, did you review the expert reports of Dr. Sodhi and Dr. Sommer?

A Yes, I did.

Q And Dr. Davies?

A Yes, I did.
Q Were you here when doctors -- you weren't here for Dr. Davies but you read his transcript?
A Yes, I did.
Q And you were here for Dr. Sodhi's and Dr. Sommer's live testimony. Correct?
A Yes, I was.
Q Based on what you've seen in this case, do you have an understanding of whether the test methods Dr. Sodhi and Sommer used are the types relied on by those of kill in the art of pharmaceutics?
A I understand that they are.
Q What level of confidence do you have in the testing and analyses from -- that were done by Dr. Sodhi and Dr. Sommer?
A I'm very confident that they showed exactly what they said they showed.
Q What do you conclude after reviewing the test that Dr. Sommer and Dr. Sodhi testified about?
A It confirms my opinion that the manufacturing process for the Impax product makes a single coated bead with a core of the active ingredient and delayed release coat directly in contact with it.
Q Have you considered -- let's talk about Dr. Davies tests.
Did you consider it, the optical microscopy

imaging?
A Yes, I did, I looked at it.
Q Can we take a look at PTX 214. What is PTX 214?
A It's an optical microscope image of a -- the 100 milligram doxycycline hyclate Impax product.
Q Now, Dr. Davies has a legend that says he has a region one, Roman numeral I core seed, and then he has a region two coating.

Do you agree with Dr. Davies that that's the structure indicated in this image?
A Yes, I think it is.
Q Have you seen any optical microscope images of the Impax product in this case that showed anything other than a core surrounded by a single coating?
A No.
Q Have you also considered Dr. Davies scanning electron microscope imaging?
A I have.
Q Can we take a look at PTX 224.

Now, do you recall this?
A Yes.
Q Can you describe what you're seeing in this image based on your opinion?
A Well, this is a very small segment of the circumference of a bead. And it's a scanning electron microscope which is

very good at picking out morphological changes on the surface of the thing it's scanning. And you'll notice that on the lower left we have the external bead -- the external bead.

Q Doctor, can I stop you. I don't want to interrupt, but but can you use your pointer to show what you're looking at?

A All right. I'm sorry.

Down here is really the outside of the bead falling away from the surface where it's been cut, so this is just what the bead will -- this space between here and here is approximately the width or thickness of the delayed release coat. Okay?

And then in here of course is the core.

And what Dr. Davies is pointing to is some areas where he says it's got talc, but you'll notice that the same coloration is throughout the layer in various places. So if indeed this is talc, and there's no confirmatory test of this, then we can assume that these are also talc regions, because talc is uniformly distributed during the coating process.

Q Do you agree with Dr. Davies legend, that in this image what's depicted is a core seed region A, in a coating, single coating region B?

A Yes.

Q Do you agree with Dr. Davies that this image could be

interpreted to indicate a layer around the core that is talc enriched?

A Well, there is talc in the entire layer. This is a single layer, and there's talc distributed uniformly throughout it.

Q And have you seen any other SCM images in this case?

A Yes.

Q Have you seen other ones? Did you see any SCM image in this case which in your view could be interpreted as a talc enriched layer around the core?

A No, I don't think so.

Q Does this SCM image provide any information that would allow one to conclude that what's surrounding the core includes what Dr. Davies has called an HPMCP derived material?

A No, there's no information that would support that here.

Q Can you explain why you believe that's the case?

A Well, there's no analysis of the components of this that would tell us whether there was HPMCP derived material. And Dr. Davies hasn't even told us what the HPMCP derived material is.

Q Have you seen any -- if we look at the area, maybe one -- this is a two micron scale. Can we see?

A Yes.

Q Let's just say this is the core. You can't really see

exactly, but just let's say that's the core.

If you went three microns from the core and including where this, all this stuff is, have you seen any evidence from Dr. Davies that chemically analyzed what is inside the region that abutts the core?

A No.

Q Do you agree that Dr. Davies images where he took an SCM of the delayed release cross-section, delayed release impact seed, and he says he washed it with acetone first, do you see any evidence in any of those images that allows you conclude that there's either a talc enriched region around the core or a HPMCP derived material around the core?

A No.

Q Now, when you were -- when you opined that what you're seeing in SCM three, which is PTX 224, that Dr. Davies designated as having a core seed with a coating, when you were opining that that does not have a delayed release -- or a stabilising coat, were you -- did you have in mind what the Court construed the term "stabilising coat" to be?

A I tried to, yes.

Q And you pointed to earlier that that definition includes that, among other things, the stabilising coat must be a layer?

A That's right.

Q And why is it your opinion that what Dr. Davies is

showing in this image is not a layer?
A Well, let's be clear. He and I agree that there is a layer. But that layer happens to be the delayed release coat. That's -- and there's no additional structure in here that would be anything close to what the patent claims is a layer of stabilising coat.
Q Now, you understand I alluded to earlier Dr. Davies' reliance on a test where he first treated Impax seeds with a 99 percent acetone, 1 percent water mixture, and then tested the surface of what remained after he shook it in the vial?
A Yes, I remember that.
Q Do you remember -- do you believe that Dr. Davies' acetone treatment method is a scientifically reliable way to analyze the structure and composition of a pharmaceutical pellet?
A No.
Q And to your knowledge, has Dr. Davies' acetone washing method for detecting an otherwise undetectable layer ever been subjected to peer review?
A Not that I know of.
Q In your experience, have you ever heard the use of a solvent washing followed by chemical analysis of the surface as a method to identify an intermediate layer outside of Dr. Davies' use of that concept in a litigation context?
A No.

Q Now, you recall that Dr. Davies -- do you recall reading that Dr. Davies pointed to a particular paper and he said that described the use of this method?
A Yes, I recall. I recall that.
Q Do you agree with that?
A No.
Q Could we go to PTX 246. PTX 246.
Do you recognize this paper?
A Yes, I do.
Q Is this the paper Dr. Davies referred to in this direct testimony?
A Yes, it is.
Q And have you read this paper?
A Yes, I have.
Q And can you explain, without going into too much detail, but why you disagree with doctor -- what Dr. Davies, Dr. Davies' statement that this publishes his method is incorrect?
A The authors of this paper were making microcapsules using polymeric material call CAB. CAB is soluable in acetone. They used the acetone wash to remove the CAB in order to determine the weight of the coating that they had applied during their application process.
Q So in this paper, once the bead was washed, did the authors purport to detect an intermediate layer in the

product that remained after the wash?
A No. What they did was they weighed the beads, washed them, dried them, and weighed them again, and calculated the percent weight loss, and said that that was the weight of the seed, A B bead that was coated during their microencapsulation process.
Q Do you have a slide that summarizes why, Doctor, you believe Dr. Davies non-peered acetone wash layer detect method is unreliable?
A I do.
MR. PACELLA: Can we see slide 10.
A Okay.
So in order to really understand what Impax's product is we have to do analysis that doesn't first destroy the product. And the acetone treatment modified the product considerably. The solvent system he used is far different from the solvent system that Impax uses in order to apply the polymeric material.
And so he's well on almost a pure acetone wash. And we'll show a little while later that some of these ingredients don't dissolve well in acetone at all.
Then his analysis focuses on a tiny fraction of the surface, and I don't think his methodology would be effectively reproduced, because we have no idea of the length of the type of shaking, the vigorousness of it. In

other words, it's being done by hand in a small bottle. So I wouldn't be able to do exactly the same thing that he did. So I don't think it's a reasonably good design experiment.

Q All right.

So let's focus first on why you believe Dr. Davies used an inappropriate solvent if his intent was to remove the entire enteric or delayed release coating. Would you have a slide that would help explain that?

A Yeah, I do.

MR. PACELLA: Could we go to slide 11.

BY MR. PACELLA:

Q Dr. Davies, please explain, but there's a lot of information on here, or can you try to distill it for Judge Martini?

A I'd be happy to.

What I did was I created a slide that looked at the hundred percent acetone on the left and the 70-30 blend of acetone, water that Impax uses in its coating process.

And then where it's blue I suggest that that's where that material will be reasonably well dissolved in the mixture. All right?

Now, talc doesn't dissolve in anything. So it's all red. TEC, triethyl citrate is freely soluable in acetone, and so it would dissolve in all the mixtures pictured here.

HPMC is a very difficult compound to get to dissolve. But it is soluable in water. But you need to be able to prepare it in a way that it will hydrate efficiently and then go into dissolution. And we know that HPMCP can dissolve in 95 percent acetone, 5 percent water, and is insoluable in pure acetone. And we don't know how much solubility we can get, but what he's done is he's gone to the extreme end, and so even some of that wouldn't dissolve efficiently in whatever his mixture was.

So if he really wanted to get the coat completely washed off, he would need to have moved down to, closer to the Impax 30-70 mixture.

Q Now, where did you get the information about the various soluabilites of the compounds that you used to put together this demonstrative?

A I looked at the four monographs that are in the Handbook of Pharmaceutical Excipients. And across the bottom of that chart lists where they are in the exhibit list.

So ITX 632 are 24, 26, 44 and 52, are the monographs for the four ingredients out of the handbook. And then we looked at Shin-Etsu, who makes HPMCP and HPMC as back up information, and they're listed here I believe as 668 and 669.

Q Where did you get the information about the solubility in 70 percent acetone, 30 percent water?

A Okay. We got that from the batch records and the QOS from the Impax ANDA. And I think that's 214-35.
Q And I believe that's one of the exhibits we looked at previously, the Impax record?
A Yes, it is.
Q In terms of the monographs, you mentioned the four of them. Those are all contained within the compilation of the Handbook 2 Pharmaceutical Excipient references that you referenced earlier at ITX 632?
A They are.
Q Now, we'll talk about the other two references. But in terms of the HPMC, you don't have something like this that says 95-5.

Now, in your expert report did you cite a reference that at that time at least in your expert report you indicated showed that you needed at least 10 percent water to dissolve HPMC?
A I did. I apologize for that.

I went back to the reference and there is no specific data, but it's been my experience if you don't have at least 10 percent water, very, very difficult to get it to go into dissolution.
Q Okay.

So now let's look at ITX 669.

Do you recognize that?

A Yes. That's for HPMCP, it's the Shin-Etsu package information or advertising information about their product.
Q And can you point out where the solubility information that's relevant to your discussion is indicated?
A It's in a table in there. I'll have to find the page number.
Q I believe it's --
A There we go. There we go.
Q -- page five.
A Thank you. Wonderful. Page 5.
Q Now, what does page 5 say about the solubility of HP 50 in acetone?
A Okay.

So what the chart does, it tries to give you an idea of what solvents would work well with the particular polymers. And if you look, it says acetone, water, 95-5, and it has a circle, and the circle says soluable. Which means that HPMC, HP 50, which is the polymer in question, is actually soluable in acetone, water, 95, this line here. Okay. Okay. Good.

It also says that acetone does not necessarily dissolve it. It allows it to swell or there is some partial solubility. Okay.

And there's several ways of interpreting that. But from reading of the Handbook of Pharmaceutical Excipients

they would say that it swells and we can go back to their definition. Okay? But partial solubility means that some of it might dissolve. Polymeric mixtures like this, because they are polymeric, have different molecular sizes. All right?

So that as you make the material, because it's made from cellulose, and it's derived, you can have much smaller molecular sizes and much larger molecular sizes. And I think that what they're trying to get at --

MR. SEPHTON: Your Honor, I would object, like to object. This is not in the expert report or in his deposition. I asked him about this brochure --

MR. PACELLA: Your Honor, --

MR. SEPHTON: -- particularly --

THE COURT: Hold on. Let me hear the --

MR. SEPHTON: -- the discussion about molecular weight having the affect on solubility, not raised at all previously.

THE COURT: Is it in his report?

MR. PACELLA: This specific, no, Your Honor, clearly the expert report covers the variable soluabilites and all that, and in the deposition I believe there are 10 pages about this issue.

THE COURT: All right.

Then leave it too.

The objection will be sustained.

A Fine.

Q Okay.

So, Dr. Kibbe, in terms of -- there's been some discussion about the difference between what this document says, swelling, or partially soluable in 95 percent acetone for HPMCP, and what the handbook says, which we can go back to it. But I believe the fact that it says insoluable, does that sound correct?

A The handbook said swellable and insoluable.

Q So does the fact that the handbook said swellable or insoluable, and that this reference says swelling or partially soluable, does that affect your opinion that Dr. Davies' use of 99 percent acetone was inappropriate?

A No. I think even if there was some partial solubility he wasn't using the best solvent mixture in order to get this material to dissolve.

Q And if you wanted to successfully remove the coating, the delayed release coating that was applied to Impax's product completely down to the core, what solvent would you use?

A Well, I would go back to Impax's blend and use a 70-30 acetone-water wash myself.

Q And you didn't conduct that experiment, did you?

A No, I didn't.

Q Why not?
A I didn't think there was any value to it. I didn't think it showed anything. And I think the experiment itself just changed the nature of the coating that was already applied and was clearly a single delayed release coat.
Q Is there a difference between trying to dissolve a single substance many HPMCP when it's a powder and you're just dissolving that on its own, versus trying to dissolve a mixture of a polymeric film that's been applied to a -- that's been applied?
A Yes.
Q Can you explain?
A The -- the solubility of something is a thermodynamic measure, and it measures how much will go in in any given amount of solvent.

Dissolution, how fast it dissolves, is a function of other variables. And one of them is the particle size or the size of the surface exposed to the solvent. And the other is how complex is that material.

And so in order to dissolve all three of these things off, you have to have a solvent that will work on all of them at the same time.
Q And Dr. Davies defended his choice of solvent for the acetone washing experiment based on his position that it was a more dilute solution in the testing conditions that were

used for this reference. Do you recall that?
A Yes. I do.
Q Do you recall -- do you agree that that's a basis to expect that Dr. Davies' choice of solvent was a correct one?
A No, I don't think so.
Q Can you explain?
A Well, first, we're not sure whether all of the HPMCP would dissolve anyhow, because it's swellable and partially soluable.

Second, we don't have any real reliable data on HPMC and how well it will re-dissolve in acetone or pure acetone.

But when you look at this chart you say, okay, acetone or 95 percent acetone, 5 percent water, I think you'd be more inclined to go with the 95-5 at a minimum. Which is five times as much water as Dr. Davies used.
Q Okay.

Can we go to ITX 668.

THE COURT: Did Dr. Davies, I don't recall, I don't think he did, in any of his testing, in terms of his attempting to dissolve the tablet, he never changed the solution, did he? He never changed it from 99 to one?

THE WITNESS: No, that's correct.

MR. SEPHTON: He used a ratio of one of these washes --

THE COURT: I know. He did it over times, five, 10, 15, 20.

MR. SEPHTON: But it was 99 percent acetone, 1 percent water.

THE COURT: Right.

Now, had he changed that ratio, do you have an opinion as to whether that might have changed the amount of coating that was dissolved?

THE WITNESS: I think if you went to a better solvent.

THE COURT: Better being more water?

THE WITNESS: More water. Because --

THE COURT: What you just said, that's it?

THE WITNESS: Yes.

THE COURT: So your opinion would be he didn't do this test, but if the solvent itself was changed to a ratio of let's say 80-20, that might have had an affect on the amount of the layer that was dissolved. Is that correct?

THE WITNESS: It would assist to get the layer dissolved, and I also would argue that it would be best to do it with a constant stirring --

THE COURT: Okay.

THE WITNESS: -- system, rather than just shaking it. From what I understand, one of his colleagues just shook it, and I would prefer to have it done it in a flask

with a stirring bar and a, you know, more consistent way of --

THE COURT: In your opinion, would it be the best ratio if you had to pick a ratio, again there's no -- Dr. Davies picked a ratio of 99 to one. Correct?

THE WITNESS: Yes, he did.

THE COURT: But if you were to have done this and you had to pick a ratio, I think your opinion, you would pick 70-30 because that was the same mix as to when they made the coating?

THE WITNESS: Yes, I would.

THE COURT: And you think by doing the same mix there's a greater likelihood more of the coating, if not all of it, would have come off?

THE WITNESS: Yes, that's what I believe.

THE COURT: So you have a variable about what the solution should be.

THE WITNESS: Yes.

THE COURT: You have a variable of how long the mixing should go.

THE WITNESS: That's correct.

THE COURT: You have the variable of how it should be mixed. Is that correct?

THE WITNESS: Yes.

THE COURT: You -- I mean whether it's stirred or

shaken or --

THE WITNESS: Yes, sir.

THE COURT: Okay. Thank you.

Go ahead.

MR. PACELLA: Thank you.

Could we have ITX 668.

BY MR. PACELLA:

Q Dr. Kibbe, could I refer you to ITX 668.

THE COURT: By the way, is there anything in any established scientific literature that Dr. Davies could have referred to to figure out what the proper ratio, stirring and/or time would have been?

THE WITNESS: I believe that if you go to the handbook and look at the solubility profiles it's a good place to start.

THE COURT: That was that --

THE WITNESS: Exactly.

THE COURT: -- this is this, what we just had, this chart?

THE WITNESS: Right.

And so he could have started with 95-5. But the problem with 95-5 is it works really well for HPMPC. But we know that HPMC is even more water loving as it were, and so you probably would want to have more water. You could do a comparative test, Your Honor, if you really -- you're really

determined, and take some beads and do it at 95-5 and some at 90-10 and some, and eventually find the correct blend.

THE COURT: Before -- before learning about Dr. Davies doing this solubility test, had you ever heard of it being done to determine what the coatings were of a pharmaceutical pill?

THE WITNESS: No. This is HPMC, it's hypromellose and it's Phamacoat, Shin-Etsu brochure, and I think the reason we want to --

BY MR. PACELLA:

Q Can I just stop you there, I just want to put on the record that what we're talking about, ITX 668, and you just identified that as the Shin-Etsu brochure for HPMC Pharmacoat?

A That is correct.

Q All right.

And I just want to ask you, what is the relevance of how does this -- what does this tell you about the solubility of HPMC?

A We all know that Pharmacoat, HPMC is soluable in water, but it has some unique properties. It's inverse in terms of temperature. The warmer the water is, the less soluable it is. The colder the water is, the more soluable it is. If you try to mix it in cold water, right away it has a tendency to aggregate and clump and you end up with lumps

like you would lumpy gravy.

So the techniques to get it to go into dissolution require you to somehow disperse it in a relatively poor solvent, and then have it gradually hydrate to become a uniform mixture. And so the 70-30 mixture of acetone-water is a relatively poor solvent for Pharmacoat. But allows it to be distributed and gradually hydrate and go into dissolution over time.

Q And how does that relate to your conclusion that Dr. Davies used the wrong solvent to attempt to wash off Impax's delayed release coating?

A I have no data to support this directly, but it's my opinion that there wasn't enough water in his acetone-water mixture to successfully dissolve the HPMC.

Q And what's the basis of that opinion?

A Because it's water soluable. And so in order to get it to go into dissolution, you first distribute it in a non-solvent situation and then you allow that solvent to take over and get it to go into dissolution. It's a difficult thing to work it.

THE COURT: Counsel, how much more do you have on your direct?

MR. PACELLA: Your Honor, I believe, I'm more than halfway, but I did have a lot of material to cover.

THE COURT: All right.

Then we'll recess for lunch. We'll be back at 1:15, please.

MR. PACELLA: Thank you, Your Honor.

THE COURT: Thank you.

We're in recess.

( After a luncheon recess court resumed ).